From: theodorams <theodorams@aol.com>
To: [redacted]ol.com>
Subject: FDA response that I should file a Citizen Petition to the FDA Commissioner Fri, Nov 17, 2017 11:31 am
Date: Wed, Jan 9, 2019 12:57 pm

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Fri, Nov 17, 2017 12:13 pm
Subject: Re: Difference of opinion on the scientific evidence the FDA relies upon to regulate radiofrequency energy emitting products such as cell phones

Dear Abiy Desta,
Thank you for your response. However I would like answers to my questions. The FDA answered some questions and I am asking for clarification. I would like a full response to the questions as my questions have been half answered.

I am asking for clarification on the answers I was given. I am glad to reword my letter to be specific to my questions, rather than asking the question. Citizens should have answers to these questions. Should I contact my elected officials to be engaged and support this? I was given answers that are not clear.

Thank you,
Theodora Scarato

FDA response that I should file a Citizen Petition to the FDA Commissioner Fri, Nov 17, 2017 11:31 am
After not getting a response

-----Original Message-----
From: CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
To: theodorams <theodorams@aol.com>
Cc: CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Fri, Nov 17, 2017 11:31 am
Subject: Difference of opinion on the scientific evidence the FDA relies upon to regulate radiofrequency energy emitting products such as cell phones

Dear Ms. Scarato,

First, please allow me to introduce myself. My name is Abiy Desta and I am the Ombudsman for the Center for Devices and Radiological Health (CDRH) at the FDA. I have been monitoring the communications between you and CDRH regarding the scientific evidence the Agency relies upon to regulate radiofrequency energy emitting products such as cell phones. From reviewing the communications it is clear to me that you disagree with how the FDA is regulating these consumer products and I don't believe further informal engagements between you and the Center will resolve the differences of opinion that exist.

The appropriate method for requesting FDA change the way it regulates cell phones and similar radiofrequency energy emitting consumer products is by filing such a request via a Citizen Petition to the FDA Commissioner as described in the Code of Federal Regulations, Title 21, Section 10.30 (21 CFR 10.30). As mentioned in this regulation, a Citizen Petition must follow the format specified for petitions in 21 CFR 10.20. You can obtain further information on this matter on the FDA Web site at this location: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm.

Best regards
Abiy Desta

Abiy B. Desta
Ombudsman
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=100&D=140&B=140&E=&S=E

From: theodorams <theodorams@aol.com>

To: Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>; Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>; Jeff.Shuren <Jeff.Shuren@fda.hhs.gov>; Mary.Pastel <Mary.Pastel@fda.hhs.gov>; Brian.Beard <Brian.Beard@fda.hhs.gov>; Bakul.Pa <Bakul.Patel@fda.hhs.gov>; theodorams <theodorams@aol.com>; Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>; DICE <DICE@fda.hhs.gov>; stephanie.caccomo <stephanie.caccomo@fda.hhs.gov>

Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov> michelle_altman <michelle_altman@lankford.senate.gov>; katherine_mayne <katherine_mayne@lankford.senate.gov>; dvora.lovinger <dvora.lovinger@mail.house.gov>; chris.meekins <chris.meekins@mail.house.gov>; karen.kudelko <karen.kudelko@mail.house.gov>; suzanne.owen <suzanne.owen@mail.house.gov>; keith.abouchar <keith.abouchar@mail.house.gov>

Subject: Letter to the FDA on the health and safety of wireless and 5G technology.

Date: Sat, Jun 2, 2018 7:06 am

Attachments: PDF Evaluation of Genotoxicity of Cell Phone Radiofrequency Radiation in Male and f the Genot d Female notoxicity e Rats and y Ce d Mice ell Ra e Following g Subchronic ncy c Exposure Po (266K), November 19, 2017 Letter to the FDA on french test reports and liability issues..pdf (16423K), Feb 3, 2018 Letter to the FDA on statement on the NTP Study.pdf (364K), The human skin as a sub-THz receiver – Does 5G pose a danger to it or not (1).pdf (1193K), 5G public health Cindy Russell 2018 first page .pdf (127K)

Dear Dr. Kassiday and Dr. Jeffrey Shuren

I am writing you in reference to FDA statements and stated opinion on the safety of wireless communications systems. My questions are in reference to the recent National Toxicology Program (NTP) Study that found "clear evidence of cancer" from radio frequency wireless radiation. (See details here).

Thank you in advance for answering these questions.

1. I am still in need of a response to my questions sent November 19, 2017, February 3, 2018, and April 5, 2018 by email. (See attached.) When will we be receiving the answers?

2. I have attached the presentation by the NTP on genotoxicity data. Is the FDA going to be doing a quantitative risk assessment on the DNA data?

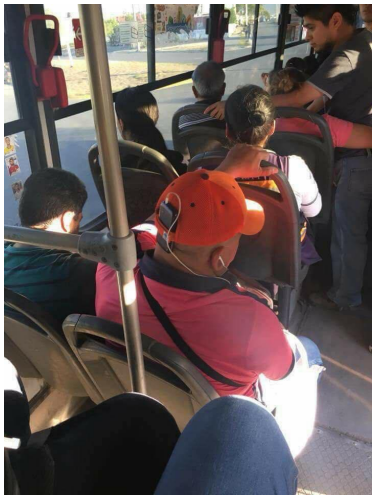
3. Is the FDA going to be doing a quantitative risk assessment on the findings of increased cancers from the NTP peer review? If so then when?

4. In a recent Congressional hearing the FCC Chair stated that "we have consulted with te FDA and others for determining what those limits should be and we are confident that our standards are ones that are healthy for consumers." See the video of that statement here https://www.youtube.com/watch?v=rk6Oy-Mw0bk&t=2s . Has the FCC consulted with the FDA since the NTP study to adress the issue of cell phone and wireless exposure radiation limits?

5. In light of the french ANFR tests showing excess radiation from phones at body contact, what steps is the FDA taking to adress the fact that cell phones and wireless devices have SARS that exceed FCC limits when devices are placed at body contact? In June and September 2017 I informed you of the results of the ANFR tests and of the ANSES scientific report. The FDA wrote back October 18, 2017 that "the information is interesting and we would like to see the experimentation in its entirety." The reports by ANFR are now posted in their entirety on the ANFR website. Will the FDA be addressing this issue of phones exceeding SAR limits when phones are used at body contact? We now have full documentation that a phone that meets SAR limits at 5 mm can fail at 0 mm distance from the body.
Note: In France several phones models are being removed from the market due to these excesses radiation issues. See a news report on the recalls here.

6. Will the FDA be updating their website with the scientific results *now peer reviewed* of the NTP finding "clear evidence of cancer"?

7. Is the FDA that children are holding wireless devices against their body such as in this video https://ehtrust.org/alert-virtual-assistant-radiation-exposure-linked-cancer-headaches-memory-unhealthy-impacts/ or in this image of a man with the phone in his hat.



8. The DNA and tumor findings of the NTP indicate non thermal effects from long term exposure as the animals were exposed at levels considered "non thermal. " What is the process by which the FDA is going to integrate this information into an opinion of the safety of exposure limits for RFR both occupational and for the public ?

9. In the NTP study heart damage was found at all exposure levels. Please see a video clip excerpt of this here https://www.youtube.com/watch?v=HtfXJFNOQFc . How is the FDA going to address this clear significant effect across all exposure groups? Will you do a quantitative risk assessment?

10. 5G technology will use millimeter waves that are known to have an effect to the skin. I attached research on this. Will their be any premarket safety testing for 5G technology? To understand the long term effect onto human health? If so please detail the research and who is performing it.

11. When did the FDA do a systematic review of the scientific evidence to evaluate impacts on human health?

12. Please See the literature review on 5G technology. What is the FDA response to this published paper?

13. What is the FDA response to the published paper on 5G and the skin?

Thank you so much for answering these questions. I have cced to Congressional staffers these questions and look forward to hearing back from you promptly.

Theodora Scarato

From: theodorams <theodorams@aol.com>

To: theodorams <theodorams@aol.com>; Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>; Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>; Jeff.Shuren <Jeff.Shuren@fda.hhs.gov>; Mary.Pastel <Mary.Pastel@fda.hhs.gov>; Brian.Beard <Brian.Beard@fda.hhs.gov>; Bakul.Patel <Bakul.Patel@fda.hhs.gov>; DICE <DICE@fda.hhs.gov>; stephanie.caccomo <stephanie.caccomo@fda.hhs.gov>

Cc: michelle_altman <michelle_altman@lankford.senate.gov>; katherine_mayne <katherine_mayne@lankford.senate.gov>; dvora.lovinger <dvora.lovinger@mail.house.gov>; chris.meekins <chris.meekins@mail.house.gov>; karen.kudelko <karen.kudelko@mail.house.gov>; suzanne.owen <suzanne.owen@mail.house.gov>; keith.abouchar <keith.abouchar@mail.house.gov>

Subject: Re: Letter to the FDA on the health and safety of wireless and 5G technology.

Date: Mon, Jun 11, 2018 4:59 pm

Dear Dr. Kassiday and Dr. Jeffrey Shuren,

I have been informed my question was not clear enough so I added a few questions to be very clear about what I am asking in relation to allowable SAR exposures from cell phones.

Additional question 1: As the FDA stated to me there was a safety factor of 50 for whole body exposure- please answer this question for clarity. In terms of SAR for cell phones themselves- **What is the Safety factor that the FDA has determined to exist in terms of localized exposure?** Please be specific - for example- respond with a SAR something like "at 6.0 w/kg over 1 gram, the FDA considers a cell phone to be emitting RF that could be harmful." or if a cell phone SAR is measured at 10 w/kg then the FDA will take action.." In other words, **please specify the cell phone SAR level that the FDA believes is harmful and exceeds the safety factor to the degree that the FDA considers the SAR harmful.**

Additional question 2: What is the FDA's stated safety factor in terms of cell phone localized SAR? Please give me a number. Is it 2 times or 5 times or 50 times? What is the safety factor the FDA has determines exists for localized SAR from a cell phone?

Additional question 3: The FDA states there is a 50 times safety factor for whole body exposure. Does this mean that at 100w/kg the FDA will act?

Additional question 4: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the testes. Please also be specific the SAR threshold that the FDA will act on in terms of exposure to testes.

Additional question 5: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the eye. Also please specific the SAR threshold value that the FDA will act on in terms of exposure to eye tissue. Does the FDA have the same SAR for eye tissue that they use for localized tissue exposure? or does the FDA use another SAR threshold value- to determine at which time they will act?

Thank you so much,
Theodora Scarato

See below the full set of questions.

I am writing you in reference to FDA statements and stated opinion on the safety of wireless communications systems. My questions are in reference to the recent National Toxicology Program (NTP) Study that found "clear evidence of cancer" from radio frequency wireless radiation. (See details here).

Thank you in advance for answering these questions.

1. I am still in need of a response to my questions sent November 19, 2017, February 3, 2018, and April 5, 2018 by email. (See attached.) When will we be receiving the answers?

2. I have attached the presentation by the NTP on genotoxicity data. Is the FDA going to be doing a quantitative risk assessment on the DNA data?

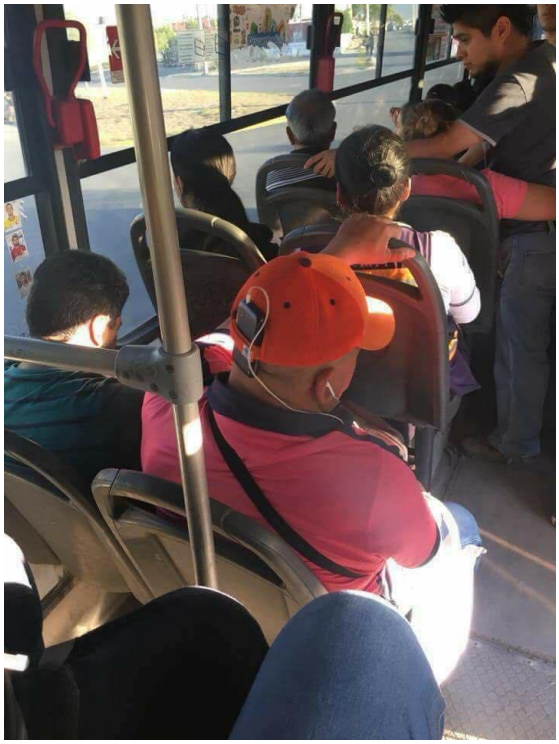
3. Is the FDA going to be doing a quantitative risk assessment on the findings of increased cancers from the NTP peer review? If so then when?

4. In a recent Congressional hearing the FCC Chair stated that "we have consulted with te FDA and others for determining what those limits should be and we are confident that our standards are ones that are healthy for consumers." See the video of that statement here https://www.youtube.com/watch?v=rk6Oy-Mw0bk&t=2s . Has the FCC consulted with the FDA since the NTP study to adress the issue of cell phone and wireless exposure radiation limits?

5. In light of the french ANFR tests showing excess radiation from phones at body contact, what steps is the FDA taking to adress the fact that cell phones and wireless devices have SARS that exceed FCC limits when devices are placed at body contact? In June and September 2017 I informed you of the results of the ANFR tests and of the ANSES scientific report. The FDA wrote back October 18, 2017 that "the information is interesting and we would like to see the experimentation in its entirety." The reports by ANFR are now posted in their entirety on the ANFR website. Will the FDA be addressing this issue of phones exceeding SAR limits when phones are used at body contact? We now have full documentation that a phone that meets SAR limits at 5 mm can fail at 0 mm distance from the body.
Note: In France several phones models are being removed from the market due to these excesses radiation issues. See a news report on the recalls here.

6. Will the FDA be updating their website with the scientific results *now peer reviewed* of the NTP finding "clear evidence of cancer"?

7. Is the FDA that children are holding wireless devices against their body such as in this video https://ehtrust.org/alert-virtual-assistant-radiation-exposure-linked-cancer-headaches-memory-unhealthy-impacts/ or in this image of a man with the phone in his hat.



8. The DNA and tumor findings of the NTP indicate non thermal effects from long term exposure as the animals were exposed at levels considered "non thermal. " What is the process by which the FDA is going to integrate this information into an opinion of the safety of exposure limits for RFR both occupational and for the public ?

9. In the NTP study heart damage was found at all exposure levels. Please see a video clip excerpt of this here https://www.youtube.com/watch?v=HtfXJFNOQFc . How is the FDA going to address this clear significant effect across all exposure groups? Will you do a quantitative risk assessment?

10. 5G technology will use millimeter waves that are known to have an effect to the skin. I attached research on this. Will their be any premarket safety testing for 5G technology? To understand the long term effect onto human health? If so please detail the research and who is performing it.

11. When did the FDA do a systematic review of the scientific evidence to evaluate impacts on human health?

12. Please See the literature review on 5G technology. What is the FDA response to this published paper?

13. What is the FDA response to the published paper on 5G and the skin?

14. **Additional question 1:** As the FDA stated to me there was a safety factor of 50 for whole body exposure- please answer this question for clarity. In terms of SAR for cell phones themselves- **What is the Safety factor that the FDA has determined to exist in terms of localized exposure?** Please be specific - for example- respond with a SAR something like "at 6.0 w/kg over 1 gram, the FDA considers a cell phone to be emitting RF that could be harmful." or if a cell phone SAR is measured at 10 w/kg then the FDA will take action.." In other words, **please specify the cell phone SAR level that the FDA believes is harmful and exceeds the safety factor to the degree that the FDA considers the SAR harmful.** Please state it in w/kg and specify ten or one gram averaging.

15. Additional question 2: What is the FDA's stated safety factor in terms of cell phone localized SAR? Please give me a number. Is it 2 times or 5 times or 50 times? What is the safety factor the FDA has determines exists for localized SAR from a cell phone? Please state the actual numerical number.

16. Additional question 3: The FDA states there is a 50 times safety factor for whole body exposure. Does this mean that at 100w/kg the FDA will act?

17. Additional question 4: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the testes. Please specific the SAR threshold that the FDA will act on in terms of exposure to testes. Either way please state the SAR limit the FDA uses to determine if they will act and please state the safety factor the FDA is applying from the FCC regulatory threshold.

18. Additional question 5: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the eye. Also please specific the SAR threshold that the FDA will act on in terms of exposure to eye tissue. Does the FDA have the same SAR for eye tissue that they use for localized tissue exposure? or does the FDA use another SAR threshold value- at which time they will act? Either way please state the SAR limit the FDA uses to determine if they will act and please state the safety factor the FDA is applying from the FCC regulatory threshold.

Thank you so much for answering these questions. I have cced to Congressional staffers these questions and look forward to hearing back from you promptly.

Theodora Scarato

From: theodorams <theodorams@aol.com>
To: theodorams <theodorams@aol.com>
Subject: Letter to Dr. Shuren: 11/2018 Questions for the FDA about the NTP study on cell phone radiation
Date: Mon, Dec 17, 2018 4:33 pm
Attachments: NTP clear cancer evidence James Lin 9-2018 Health Matters IEEE Microwave Magazine.pdf (1478K)

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: Lindsay.Lloyd <Lindsay.Lloyd@fda.hhs.gov>
Sent: Tue, Nov 6, 2018 8:33 am
Subject: Re: Questions for the FDA about the NTP study on cell phone radiation

Dear Ms. Lloyd,

Thank you for getting back to me. I updated the questions for Dr. Shuren a bit and added two new ones. I would like an answer soon, being this is a timely issue. I hope to receive a response by the end of the week. The FDA has issued a statement widely cited in the media and I am asking for the documentation that underlies the statements made by the FDA . I am also asking for an explanation as to what seems to be a contradictory stance. The FCC limits are based thresholds for harm determined from animal studies from the 70's.

Theodora Scarato

6 Hillside Road Unit S
Greenbelt MD 20770

Dear Mr. Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health

1. Please send the technical report or full comments and explanation that explain that explain why the FDA disagrees with the findings of clear evidence of cancer regarding the schwannomas of the heart in male rats. The FDA says "After reviewing the study, we disagree, however, with the conclusions of their final report regarding "clear evidence" of carcinogenic activity in rodents exposed to radio frequency energy." The peer reviewers and scientists are listed on the NIH NTP report but there is no scientist names listed under the FDA statement nor is there a proper technical report with citations. We would like the FDA's technical scientific comments and the identification of which FDA scientists "disagree " as we were unaware there was a team of scientists at the FDA working on this issue.

2. Would the FDA agree with a determination that the schwannomas of the heart in male rats were "some evidence" or does the FDA say they are "no evidence"

3. Does the FDA agree with the determination of "some evidence" for the brain gliomas in the male rats?

4 The FDA stated of the March 2018 peer review "The FDA was not a participant in that process, but was invited to observe the panel discussions, which included an assessment of the study methods and data by a panel of 15 peer reviewers to determine the basis of evidence for the final report." So my question is this --as two FDA officials were in the room during the entire March peer review and had an opportunity to speak and offer comments (and one FDA staff did in fact make a statement and a rather astute statement that the exposure should consider dose over time as I recall) Did the FDA share their comments of disagreement with the NTP findings at any time? Including before and/or after the peer review?

4. Did the FDA inform the NIH/NTP at any time over the last twenty years that animal research would not be sufficient to determine risk to public health from cell phone radiation? And that the FDA would consider the NTP designed study to have findings irrelevant to humans?

5. The November 1, 2018 statement on the NTP final report says, "We have relied on decades of research and hundreds of studies to have the most complete evaluation of radiofrequency energy exposure. This information has informed the FDA's assessment of this important public health issue, and given us the confidence that the current safety limits for cell phone radiofrequency energy exposure remain acceptable for protecting the public health." **Please share with us this report or evaluation that shows the "complete evaluation of radiofrequency energy exposure" done by the FDA.**

6. **Why is the FDA centering on whole body exposure?**

The FDA states that "we only begin to observe effects to animal tissue at exposures that are 50 times higher than the current whole body safety limits set by the FCC for radiofrequency energy exposure." However, the NTP study was designed to look at localized tissue SARs --from the phone near the body- **so called near field exposure**. People certainly have areas of their bodies that will experience far higher levels than whole body SAR's. Clearly people's brains will get higher SARs than whole body exposure limits. **Why is the FDA centering on whole body exposure?** The study was designed to look at the SARs to tissue i**n the near field not far field.** As Dr. Lin who was a peer reviewer stated in his article attached to this email:

> "The current RF exposure guidelines of 1.6 or 2.0 W/kg are promulgated with a reduction factor of 50 as a safety margin for the general public and to provide protection against presumed hazardous biological effects in humans [5], [6]. The finding that RF exposure could lead to dose-dependent cancer development at levels that are the same or three times above current exposure guidelines is significant. This implies that the safety margin may be no more than a factor of three. In fact, one recommendation (IEEE C95.1-2005) has a set of guidelines under controlled environments that allows local SARs of the brain and heart to be as much as 10 W/kg [7]. An SAR of 10 W/kg is considerably higher than the 1.5, 3.0, and 6.0 W/kg used in the NTP study."
> (See full pdf online here, IEEE link here)

7. Why is the FDA not acknowledging that people can be exposed to localized SARs of well over 1.6 w/kg. The U.S. also has an "occupational" SAR limit, which is 8.0 W/kg averaged over any 1 gram of tissue for the head and body and 20.0 W/kg averaged over 10 grams of tissue for "extremities." Thus the NTP study used exposures UNDER FCC limits.

- I personally have repeatedly contacted the FDA with the French government research that establishes without a doubt that when cell phones are used at body contact, the SARs into localized tissue could reach far beyond FCC limits of 1.6. The French tests shows the SARs could be up to 5 times higher ! when people use phones at body contact in conditions of high power- for example, a phone streaming video in a room with a low signal.
-

- See a prime example of consumer use here (man with phone in hat in bus) and here (woman streaming video for child which changing baby's diaper.) In these two scenarios, the phone is directly to the skull without an ear to provide spacing. ***Why is the FDA maintaining a conversation about whole body exposure when this is about local exposures (as stated the NIEHS) and when French tests document that local tissue SARs can exceed the FCC limits and be as high as 14 to 22 w/kg (converting the ten gram to one gram average)?***

And finally
8. What is the FDA's opinion on the fact that short term animal studies were used as the basis of our FCC limits?

The FDA is stating that NTP animal data is not relevant to humans but the current FCC limits are based on animal studies *done in the 70's and 60's. Research primarily on small mammals- mice, rats and bunnies- are the basis for the determination of the threshold for the so called "thermal effect. Does the FDA also think that that the animal data that underpins our current FCC limits is not relevant to humans?*

Following the logic of the FDA that animal research cannot be directly correlated to human physiology (which I agree with by the way as you cannot directly apply the risk ratios and we need to do a quantitative risk assessment), this then means our FCC limits are irrelevant to humans as well.
NOTE: The animal studies referenced in the standards used by the FCC to define regulations on radiofrequency limits in place now were not performed as carefully controlled as the NTP's 30 Million dollar study. No study could ever come close to the NTP in terms of controlling the exposure.

- According to the FCC, "the FCC's guidelines are based on recommended exposure criteria issued by the NCRP and ANSI/IEEE". The current FCC exposure limit was adopted by the FCC in 1996- based substantially on the IEEE C95.1-1991 but officially ANSI/IEEE C95.1-1992 which is identical as the U.S. government's exposure limit regulation.
- This means that effectively the standards adopted in 1996 are really from 1991 documents and if you look at the standards document, ***you can see the research cited is on rats, mice and two with squirrel monkey for very short term exposure***. Go to table A1. The IEEE C95.1-1991 and ANSI/IEEE C95.1-1992 used to inform NCRP Report.
- According to the FCC, the exposure limits, adopted at the recommendation of the Environmental Protection Agency and other federal health agencies are primarily based on National Council on Radiation Protection and Measurement (NCRP) Report No. 86 "Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields" This report includes sections on developmental effects and considers children in deriving the exposure limits.
- Pg 286 of NCRP Report No. 86 "Exposure limits for RFEM radiation for the human population are based to a great extent on data obtained from exposures of small animals to

plane waves. Under such conditions, it is relatively easy to quantify the maximal rate of energy absorption by analytical or experimental means."

- NCRP Report No. 86 "The body of scientific knowledge of biological effects of RFEM
- irradiation, although containing several thousands of archival reports, is fragmented: it is preponderantly based on acute exposures at relatively few frequencies." In the absence of human data, it is necessary to turn to data on subhuman species… The carrier frequencies associated with behavioral disruption range from 400 MHz to 5.8 GHz. These studies were performed on species ranging from laboratory rats to rhesus monkeys, and involved nearfield, far-field, multipath, and plane-wave fields, both CW and modulated. In spite of marked differences in field parameters, thresholds of behavioral impairment were found within a relatively narrow range of whole-body-averaged SARs ranging from -3 to -9 W /kg."

Animal data was used to develop FCC limits as stated in IEEE C95.1-1991 (Revision of ANSI C95.1-1982) IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz :

- "The existing MPEs are based on the threshold for behavioral disruption with acute (short-term) exposures of experimental animals."

- "As was the case for ANSI C95.1- 1982 [B1], IEEE Subcommittee IV has had to turn to data collected on subhuman species, fully realizing that the small mass, limited physiological capacity, and unusual body dimensions of most furred laboratory animals strongly influence not only the SAR at any given frequency but also the character and magnitude of biological response. It is important to realize that not only is there an uncertainty inherent in measurements of the responses of animals, but extrapolation of these measurements to human beings may be difficult."

Putting it simply, **our FCC limits are based on data from short term exposures to animals.** The FDA asked the NTP to do animal studies to consider long term exposures. The NTP did just that. Now the FDA is rejecting the findings as irrelevant to thermal versus non thermal impacts on human health because it is an "animal study."

I am asking the FDA to explain these contradictory positions.

----Original Message-----

From: Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
To: theodorams <theodorams@aol.com>
Sent: Tue, Nov 6, 2018 7:28 am
Subject: RE: Questions for the FDA

Thank you for taking time to write me. I will get this logged today.

Is there a name and mailing address for you that I can use for the official log of this question/email?

Lindsay

Lindsay Lloyd
Office of the Center Director
Center for Devices and Radiological Health

From: Kassiday, Daniel F. H. <Daniel.Kassiday@fda.hhs.gov>
To: 'theodorams@aol.com' <theodorams@aol.com>
Cc: O'Hara, Michael D <Michael.OHara@fda.hhs.gov>; Jung, William <William.Jung@fda.hhs.gov>; Ochs, Robert <Robert.Ochs@fda.hhs.gov>; CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: RE: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.
Date: Wed, Oct 18, 2017 1:59 pm

Dear Ms. Scarato:

Thank you for bringing these issues, documents, and videos to our attention. We are responding to both your June 13, 2017 email and the additional questions submitted on September 8, 2017.

In your June 13 email you said:

> "I have attached below a press release regarding the data that the French government released testing data showing that cell phones violate cell phone radiation limits when tested directly against the body.
>
> This information from France is clear evidence that cell phone testing is inadequate to protect consumers from the radiation limits for cell phones we have in place. Children and pregnant women place these phones directly on their bodies, store them in bras took them into spandex pants and all of these positions are not tested by the manufacturers."

Response to the preceding text:

We have asked the French Agency for a discussion of their studies and findings and conclusions. However, they have not responded as of the writing of this response.

We would like to bring your attention to an opinion from the French Agency for Food, Environmental and Occupational Health and Safety (June 20, 2016). "According to the available studies on the health effects of radiofrequencies that were analyzed, the collective expert appraisal work group concluded as to a possible effect of radiofrequencies on: 1. cognitive functions: the results showing acute effects were based on experimental studies with well controlled methodologies. 2. Well-being: these effects may however be linked to the use of the mobile telephones rather than to the radiofrequency radiation they emit." In both cases the French working group concluded that there is limited evidence to conclude as to whether radiofrequencies have an effect on cognitive functions or well-being. SCENIHR (2015) has also looked at these kinds of studies and determined that there is not a great deal of evidence.

The working group for the French Agency for Food, Environmental and Occupational Health and Safety also concluded that "it is not possible to conclude from the current data as to whether or not radiofrequency radiation has an effect on children's: 1. behavior, 2. auditory function, 3. Teratogenic effects and development, 4. male and female reproductive systems, 5. carcinogenic effects, 6. Immune systems, and 7. systemic toxicity."

Below we will respond to the specific questions stated in both of your emails:

Question 1:

> I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact. The FDA is aware that people use cell phones resting on their legs or on chests and therefore the FDA needs to be aware that the American public is being exposed to radiation levels exceeding our government guidelines. Please see this picture taken at an airport just this week. Note the laptop resting on this man's chest.
>
> Please see these images from Maryland public Schools of students with devices on their body as well as how people typically wear their phones when they work out.
>
> I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact in light of the fact that Americans are placing radiating cell phones and wireless devices directly on their bodies in violation of the FCC instructions and therefore exceeding FCC SAR values in their body.

Response to Question 1:

The information is interesting and we would like to see the experimentation in its entirety. However, as mentioned above we have not discussed the experimentation with the French Agency for Food, Environmental and Occupational Health and Safety. The experimentation has not been commented on by expert review groups or by the Federal Communications Commission. At this time we have not formulated an opinion about the differences in the testing protocols used in France versus the United States. Currently we believe that the safety limits are adequate to protect the public.

Question 2:

> In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement, "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like

you were saying that the FDA's position is that "it is OK" if this regulatory limit was exceeded because of this "large safety factor". Is that what you meant in your response?

Response to Question 2:

It is unclear what the SAR is when a phone or other electronic product is placed on the abdomen of pregnant women. The French Agency for Food, Environmental and Occupational Health and Safety experiment has not been fully reviewed so differences in their SAR values and SAR values generated from current testing methods are unknown. The 2015 expert review by SCENIHR provides a good summary of a large amount of data. According to the SCENIHR expert review group "Most recent studies investigating effects on pregnancy outcome and development of the offspring have been large and well conducted, and so can provide very useful information. These studies found that low level prenatal and early postnatal exposure to a variety of RF signals was not associated with any adverse outcome". Additionally, the Norwegian Mother and Child Cohort Study (Epidemiology July, 2015) concluded that there is no association between maternal prenatal or preconception cell phone exposure and any of the studied pregnancy outcomes. These studies suggest that the current safety limits are adequate to protect pregnant mothers and offspring.

Question 3:

So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor."?

Response to Question 3:

FDA is not saying that it is OK to exceed a regulatory limit. We stated that there is a large safety factor built into these regulatory limits. Please contact FCC regarding their compliance testing and enforcement policies regarding their regulatory limits.

Question 4:

And if the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor, *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? Could you please specify in terms of SAR as to the SAR at which the FDA will take action. For example is it a SAR of over 4 w/kg or 7 w/kg or 21 w/kg or more?

Response to Question 4:

The current safety limits established by the FCC are adequate to protect the public based on the peer reviewed literature. Please contact FCC regarding their compliance testing and enforcement policies regarding this regulatory limit.

Question 5:

What is the SAR limit at which time the public will be informed by the FDA that cell phones violate US regulatory SAR limits?

Response to Question 5:

At this time the FDA has no concerns about the regulatory safety limit set by the FCC. FDA has not established a performance standard for mobile phone products and thus we have not set any regulatory limits regarding RF emissions. Regarding notifications, the details of FDA's electronic product radiation control authorities are available on our FDA basics website at: https://www.fda.gov/AboutFDA/Transparency/Basics/ucm193950.htm.

Question 6:

I am included a chart so that you can see the cell phone, make and model and the SAR amount documenting how each phone violates SAR limits. Please see the document on this webpage but please note that the 0 mm SAR listed is per the European 10 gram averaging. Therefore the equivalent US FCC 1 gram averaging SAR is likely over 2 times the amount listed here.

I want to make you aware that Dr. Marc Arazi came to the United States and presented a lecture on these SAR violations. Please watch the lecture here. https://ehtrust.org/cell-phones-violate-radiation-limits-doctor-calls-urgent-action-update-cell-phone-radiation-tests/. I would like to ask if the FDA had watched this lecture?

Response to Question 6:

Yes, at least two FDA employees have watched that lecture video.

Question 7:

I continue to ask that the FDA update the out of date webpages. Please update these webpages. Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors." Why is the FDA still posting updated information?

Response to Question 7:

The webpage titled, Cell Phones Health Issues, links to an FDA Consumer Magazine article with the title, "No evidence linking cell phone use to risk of brain tumors". There have been several major epidemiology studies that add supporting evidence for that statement. The National Cancer Institute's Fact sheet on cell phones and cancer risk (https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/cell-phones-fact-sheet) discusses the scientific evidence regarding cancer risk and is attached for your convenience. FDA continues to believe that the preponderance of the evidence suggest that the existing safety standards for electromagnetic radiation are adequate to protect the general public.

We hope that our responses adequately address your concerns regarding the issues you raised.

Daniel Kassiday
SME: Electronic Product Radiation Control

Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-5865
daniel.kassiday@fda.hhs.gov

the agency to the view expressed.

For general information about electronic products, please visit the FDA website http://www.fda.gov/Radiation-EmittingProducts/default.htm. For Accession number status, please call (301) 796-6627. For assistance with eSubmitter please write to: esubmitter@fda.hhs.gov.

From: theodorams@aol.com [mailto:theodorams@aol.com]
Sent: Friday, September 08, 2017 10:19 AM
To: theodorams@aol.com; Kassiday, Daniel F. H.
Cc: O'Hara, Michael D; Jung, William; Ochs, Robert; CDRH Ombudsman; alonzo.washington@house.state.md.us; alonzo@alonzowashington.com; jamie.raskin@senate.state.md.us
Subject: Re: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

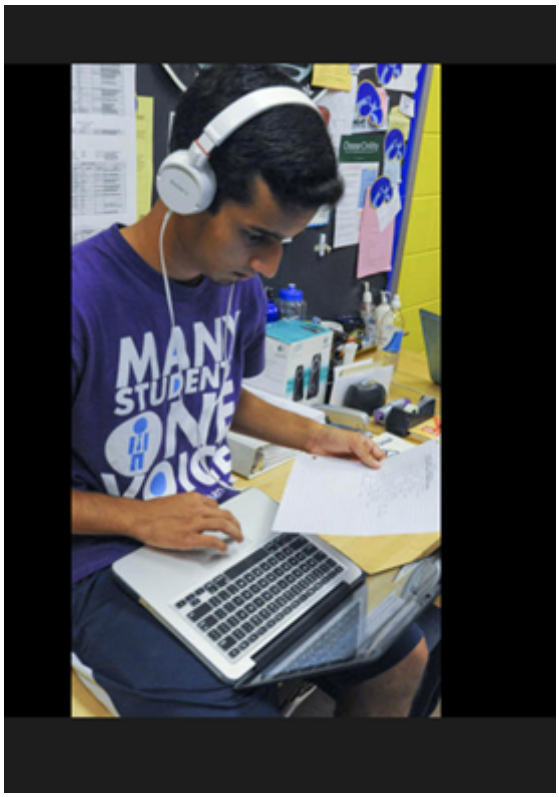
Dear Dr. Kassiday,

I have not received a response to the letter I sent Tue, Jun 13, 2017 9:09 am (see below this email the email I sent several months ago still unanswered).

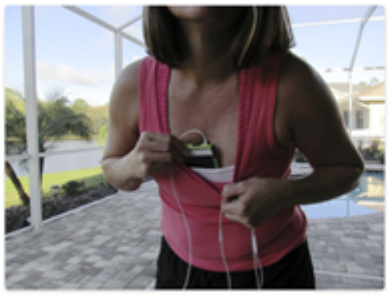
I will reiterate the questions and add a few more.

1. I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact. The FDA is aware that people use cell phones resting on their legs or on chests and therefore the FDA needs to be aware that the American public is being exposed to radiation levels exceeding our government guidelines. Please see this picture taken at an airport just this week. Note the laptop resting on this mans chest.

Please see these images from Maryland public Schools of students with devices on their body as well as how people typically wear their phones when they work out.


MANY
STUDENTS
ONE
VOICE

iPhone slips into cami bra pocket easily.



Closer view of the layers and iPhone in pocket.

I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact in light of the fact that Americans are placing radiating cell phones and wireless devices directly on their bodies in violation of the FCC instructions and therefore exceeding FCC SAR values in their body.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that "it is OK" if this regulatory limit was exceeded because of this "large safety factor". Is that what you meant in your response?

3. So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." ?

4. And if the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor., *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits?

Could you please specify in terms of SAR as to the SAR at which the FDA will take action. For example is it a SAR of over 4w/kg or 7 w/kg or 21 w/kg? or more?

5. What is theSAR limit at which time the public will be informed by the FDA that cell phones violate US regulatory SAR limits?

6. I am included a chart so that you can see the cell phone, make and model and the SAR amount documenting how each phone violates SAR limits. Please see the document on this webpage but please note that the 0mm SAR listed is per the European 10 gram averaging. Therefore the equivalent US FCC 1 gram averaging SAR is likely over 2 times the amount listed here.

7. I want to make you aware that Dr. Marc Arazi came to the United States and presented a lecture on these SAR violations. Please watch the lecture here. https://ehtrust.org/cell-phones-violate-radiation-limits-doctor-calls-urgent-action-update-cell-phone-radiation-tests/ . I would like to ask if the FDA had watched this lecture?

8. I continue to ask that the FDA update the out of date webpages. Please update these webpages. Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors." Why is the FDA stil posting updated information?

Thank you so much. I would appreciate an answer to these questions. I am ccing my elected officials who are also interested in the answer to these questions.

Sincerely,

Theodora Scarato MSW

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>
Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Tue, Jun 13, 2017 9:09 am
Subject: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

Dear Dr. Kassiday,

I have attached below a press release regarding the data that the French government released testing data showing that cell phones violate cell phone radiation limits when tested directly against the body.

This information from France is clear evidence that cell phone testing is inadequate to protect consumers from the radiation limits for cell phones we have in place. Children and pregnant women place these phones directly on their bodies, store them in bras took them into spandex pants and all of these positions are not tested by the manufacturers.

1. I am writing to ask what the FDA's response is to this information just released from France showing violations of SAR when phones are tested at body contact.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that it is OK if this regulatory limit was exceeded because of this "large safety factor". So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." And if so, *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? (SAR 4w/kg or 7 w/kg or 21 w/kg? or more?). What is the FDA limit at which time the public will be informed? Clearly most people use phones on their body and teens sleep with phones on their chests. Please respond to each question in this paragraph.

I appreciate your response in advance.

Thank you very much,

Theodora Scarato

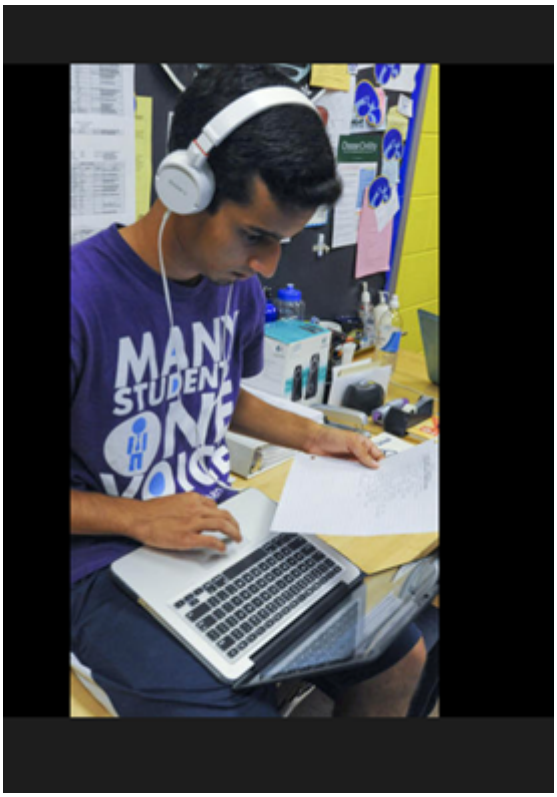
See press release on French data and prior communications below.

Cell Phone Radiation Scandal: More Exposure Than Manufacturers Claim

"PhoneGate" French government data reveals 9 out of 10 phones tested exceed regulatory limits

(Washington, DC) Under court order, the National Frequency Agency (ANFR) of France has just disclosed that most cell phones exceed government radiation limits when tested the way they are used, next to the body. Manufacturers are not required to test phones in shirt or pants pockets. French government tests on hundreds of cell phones reveal that in 2015, 9 out of 10 phones exceed the manufacturer's reported radiation test levels when re-tested in positions where the phone is in contact with the body. The government had refused to disclose these test results until the court order.

On June 1, 2017, ANFR



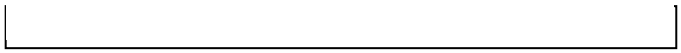
Children handed cell phones as toys.

posted the details of the make, model and test results for each phone that was tested, after months of legal action by French physician Dr. Marc Arazi. Arazi's request for the information was initially denied. Popular brands such as Apple, Motorola, Samsung and Nokia were among the cell phone models tested. When tested in contact with the body, some phones have test results as high as triple the manufacturer's previously reported radiation levels.
"As a physician, I am deeply concerned about what this means for our health and especially the health of our children. People have a right to know that when cell phones are tested in ways people commonly use phones – such as in direct contact with their body – the values exceed current regulatory limits. This is a first victory for transparency in this industry scandal," commented Arazi.

Ricocheting in headlines throughout France, Arazi and his colleagues have coined the situation as "PhoneGate" because of the parallels to "Diesel Gate" – the Volkswagen emissions saga. Devra Davis, PhD, President of Environmental Health Trust explained, "Volkswagen cars passed diesel emission tests when tested in laboratory conditions, but when the cars were driven on real roads, they emitted far more fumes. In the same way, every one of these cell phones 'passed' laboratory radiation SAR tests. These phones are legally considered compliant. However, when these phones are tested in the ways that people actually use them in real life, such as in your jeans pocket or bra, the amount of absorbed radiation emissions in our bodies violates the regulatory limits."

"This is an enormous international scandal. This is not only about France and Europe, as this applies to all persons who use cell phones in every country. If phones were tested in the ways we use them, they would be illegal," stated Dr. Davis, pointing out that these findings were replicated earlier by a US FCC certified laboratory as part of an investigation by the Canadian Broadcasting Corporation. Findings of higher radiation levels than expected (and even higher after phones are fixed) were also documented by the Holon Institute of Technology in

Israel and featured on Israeli news.



"Far more concerning is that the regulatory limits do not protect the public from adverse health effects related to long-term exposures," Davis commented, pointing to recently published research. A study in the American Journal of Epidemiology found cell phones associated with a doubled risk of glioma, a type of brain cancer. Studies performed by the US National Toxicology Program found glioma and DNA damage increased in rats exposed to long-term cell phone radiation.

"I see children cradling cell phones in their laps as their mothers do grocery shopping. Teenagers are sleeping with cell phones placed on their chest or directly beside their heads all night long. Pregnant women put cell phones and wireless devices on their abdomen. Parents have a right to know that when children use cell phones in these ways, their bodies are absorbing wireless radiation at levels that exceed limits set for adults 20 years ago," stated Theodora Scarato, Program Director at Environmental Health Trust, referring to how the American Academy of Pediatrics has repeatedly called on the US Government to update cell phone testing to reflect current use patterns. The American Academy of Pediatrics has issued clear recommendations to reduce cell phone radiation exposures to children.

The Public is Unaware

France's National Agency of Health Security of Food, Environment and Labour (ANSES) July 2016 report "Radiofrequency Exposure and the Health of Children" conceded that the public is largely unaware of instructions to keep a distance between cell phones and anyone's head and body. ANSES stated that it was "unlikely that people, especially children, are aware of the conditions of use close to the body, as defined by manufacturers."

The Canadian Broadcasting Corporation (CBC) independent survey of more than 11,000 Canadians found that more than 80 percent were unaware of manufacturers' recommended separation distance and 67 percent admitted they carry their phones against their bodies.

The newly released French data is also corroborated by the 2017 independently commissioned investigation by the Canadian Broadcasting Corporation that tested popular cell phones in a US government certified testing laboratory and found SAR values surpassed the US and Canadian allowable SAR values when the phones were tested in body contact positions. In response to the CBC report, manufacturers stated they were fully compliant.

The Wireless Industry Argues "No Evidence" To Update Testing Protocols

Read what Apple states here -and you can see in example of how the SAR looks different depending on the tissue averaging at this
link https://www.apple.com/legal/rfexposure/iphone5,1/en/

The CTIA, the wireless industry lobby group is opposed to mandatory disclosures about the manufacturer's instructions and also is opposed to updating cell phone radiation testing methods to include body contact positions ***such as were performed by the French government.*** The CTIA argued that "there is no reliable evidence proving that current testing protocols fail to ensure compliance with RF standards, " in their submission to the US Federal Communications Commission concerning the FCC Docket on Human Exposures to Radiofrequency Radiation. The CTIA stated that "a zero-measuring requirement would not accurately mimic real usage or increase safety."

In California, the City of Berkeley was sued by the CTIA, a wireless industry lobby group, when the City passed an ordinance mandating consumers are informed of these manufacturers' instructions by retail stores. The CTIA argued that the "Right To Know Ordinance" violated free speech rights and recently lost their case in court when the judges ruled that the Ordinance was "in the public interest".

After litigation by UC Berkeley public health professor Dr. Joel Moskowitz, the California Department of Public Health (CDPH) released cell phone guidance that the Department scientists had drafted, but withheld from publicly posting for seven years. The guidelines aimed inform the public from possible health impacts from cell phone radiation.

Litigation is moving forward involving more than a dozen people in the U.S. who claim their brain cancer is related to their cell phone use. In Italy, a recent court ruling recognized a link between cellphone use and brain tumors and granted lifetime compensation to a man who developed a brain tumor after 15 years of work related cell phone use.

"Why does the public have to sue to get this information?" Scarato asked. "And what about children in schools? The Maryland State Children's Environmental Health and Protection Advisory Council has recommended that schools reduce radiofrequency radiation exposures to children by installing wired networks rather than Wi-Fi, same as in Cyprus, France and Israel. Yet at the same time, schools are now allowing or even insisting children bring cell phones into classrooms. I am sure most of those children are carrying these phones from class to class in their pockets close to their body. They are not aware of the radiation exposures."

Specific Absorption Rate Testing

Before a cell phone model is permitted to go on the market for sale, its manufacturer performs Specific Absorption Rate (SAR) tests to evaluate the radiation levels. SAR values are expressed in terms of watts per kilogram (W/kg) and are intended to measure the amount of cell phone radiofrequency radiation absorbed by the body when using a wireless device. SAR tests are performed in laboratories by measuring the SAR in a test dummy filled with liquid. The European Union regulations allow a maximum of SAR 2.0 W/kg. The United States and Canada allow a maximum of SAR 1.6 W/kg. Every cell phone is rated with a specific SAR value, and many countries mandate that these SAR values be prominently displayed to consumers on cell phone packaging.

Current wireless device SAR compliance testing regulations allow manufacturers to put a separation distance (usually about 15 mm) between the phone and the test dummy. Cell phone manufacturers are not required to test cell phones for SARs in positions which mimic direct contact between the phone and the body.

ANSES reported the following findings: In 2015, 89 percent of tested cell phones had a SAR greater than the maximum limit value of 2 W/kg and 25 percent had a SAR greater than 4 W/kg.

See below the French government test data. It is in French so you can scroll to the right to see the column called "DAS tronc (au contact)" which refers to the testing done against the body at "contact" position.

This information is found online here and you can download a spreadsheet of the information.

Calls For Continued Policy Action

Since 2010, France law has ensured that SAR levels are placed prominently on cell phone packaging and the sale of cell phones was banned for young children. French legislation in 2015 included several new policies aimed at reducing exposure to radiofrequency radiation. Arazi called on the Health and Environment Ministers and Consumer Affairs and Fraud Prevention Agency to take immediate action on this new information by informing the public and issuing new protective policies.

Link to the French ANFR Website with full details on cell phones/make/model

ANFR Cell Phone SAR Measurements (PDF)

Link to France's National Agency of Health Security of Food, Environment and Labour Report on Radiofrequency and Children (In French)

English Translation of ANSES Report Section on Cell Phone Studies

NEWS REPORTS

Scandal about mobile radiation: Mobile Phones rays more than manufacturer's claim, Forskning.dk, June 7, 2017

Phones: Test bench or bench?, Journal of The Environment , June 7, 2017

Mobile phone: reassuring results that do not reassure everyone, Journal of Internal Medicine, Paris, June 7, 2017

Electromagnetic waves: Do mobile phones meet standards? Science Avenir, Paris France, June 7, 2017

France publishes the results of tests carried out on 379 GSM, Belgium News, June 3, 2017

Mobile phone: after the publication of ANFR data, Dr Marc Arazi points to irregularities, The Daily Health, June 2, 2017

Suspicions about Mobile Phones Le Monde , December 23, 2016

Phonegate: A first victory with the publication by the ANFR of the SAR, Press Release by French physician Marc Arazi, June 1, 2017

I apologize for the delay.

Your Follow up Questions To The FDA in blue

FDA answers to follow up questions are in red

I asked:**Will the FDA be updating it's website to include the NTP study results on radiofrequency radiation?**

The FDA answered:Our conclusion that current radiofrequency (RF) exposure limits adequately protect the public health has not changed based on the draft National Toxicology Program (NTP) report about a portion of NTP's study. We do not anticipate a website update on the NTP study before NTP publishes a final report regarding the complete study.

My Follow Up Question 1. : The results on the brain and heart cancers are final. They are not a draft In addition the research showing a genotoxic effect are now being added to the report. Even if all the other findings show "no effect" this is a significant finding. Why is the FDA waiting when children and pregnant women are actively exposing themselves to this radiation unaware that they could be racking up hours of exposure.

FDA answer to Follow-up Question 1: The results of the NTP study have not been published as a final document for the partial experiment discussed publically by the NTP nor have they been peer reviewed in the literature. Likewise, the genotoxicity experiments have also not been released publicly nor have they been peer reviewed. The data that has been released by the NTP is only a small subset of a much larger study. While the results add to the body of data on this topic they are not evidence that there is any risk of adverse health effects when exposures are at or below current exposure limits. When we have evidence of a public health hazard or significant risk, FDA has not hesitated to issue and disseminate appropriate safety notices. Our conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 2. Please explain how the FDA arrived at that conclusion?

FDA Answer to Follow-up Question 2: While the experiments are interesting and well performed, the results are not clear and conclusive when compared to whole body or partial body RF exposures that comply with the existing safety limits. The lowest whole body RF exposures tested in the NTP experiment are much higher than the allowable whole body exposure limit. There are differences between the experimental controls and the historical controls that further limit the conclusions reached. Our conclusion that the current RF exposure limits adequately protect the public health is not altered by the available information related to the NTP study.

Why is the FDA not considering the evidence showing fertility damage from wireless and cellphones? Specifically the research on impacts on sperm DNA at non thermal levels, impacts on the ovaries and the fact that the NTP study found the exposed group had offspring with lower birth weight. See research study found here in the drop down:http://ehtrust.org/science/research-on-wireless-health-effects/

We have looked at the papers you identified. Those studies suffer from many confounding factors that significantly limit or eliminate their impact. There is insufficient evidence available to establish adverse health effects, including when these studies are taken into account.

My Follow Up Question 3. So you are stating that all these studies are insufficient. On what grounds?

FDA Answer to Follow-up Question 3 part 1: Peer-reviewed papers are evaluated for any adverse effects reported to be caused by RF exposure. The relative strength of those papers' conclusions must be considered. Examples of factors that may weaken the utility of a paper include: the study design, study protocol violations, RF exposure sources, the dosimetric methods, SAR determination, thermometry, reproducibility of RF emissions, reproducibility of all environmental factors (temperature, air flow, vibration, etc.), differences with historical controls and recall bias. Based on the individual papers and analysis by expert review panels we conclude that the current RF exposure limits adequately protect the public health. This includes reproductive health.

What do you think of this study please in particular as the majority of studies showed an effect.

Houston B., et al. "The effects of radiofrequency electromagnetic radiation on sperm function." Reproduction, 2016.

- Among a total of 27 studies investigating the effects of RF-EMR on the male reproductive system, negative consequences of exposure were reported in 21. Within these 21 studies, 11 of the 15 that investigated sperm motility reported significant declines, 7 of 7 that measured the production of reactive oxygen species documented elevated levels and 4 of 5 studies that probed for DNA damage highlighted increased damage, due to RF-EMR exposure. Associated with this, RF-EMR treatment reduced antioxidant levels in 6 of 6 studies that studied this phenomenon, while consequences of RF-EMR were successfully ameliorated with the supplementation of antioxidants in all 3 studies that carried out these experiments.

FDA Answer to Follow-up Question 3 part 2 – re: Houston et al: Thank you for directing us to the Houston et al. "The effects of radiofrequency electromagnetic radiation on sperm function" review paper. We find this scientific opinion of this review paper to be interesting and the tabulation of the available data from the cited references useful. The paper does not extensively cover the confounding factors present in the papers reviewed. This appears to be because it is a review article that's purpose is the development of a possible mechanism of action. The authors stated that, "we explored the documented impact of RF-EMR on the male reproductive system and considered any common observations that could provide insights on a potential mechanism". The authors also acknowledge that research to date is not conclusive. In their conclusion, they say, "to date, contradictory studies surrounding the impact of RF-EMR on biological systems maintain controversy over this subject". The review's authors' proposed two-step mechanism of action and their call for further laboratory research are interesting. While the opinion of the authors contributes to the body of knowledge on this topic it alone does not change the current understanding of mechanism of RF action nor does it prove there is an adverse effect of RF exposure that complies with the limits on male reproduction. The current RF exposure limit adequately protects the public health.

Additionally, a recent paper by Lewis adds some epidemiological evidence that there is no adverse effect from RF exposures from cell phones. Please see, Lewis, R. C., et al. (2017). "Self-reported mobile phone use and semen parameters among men from a fertility clinic." Reprod Toxicol 67: 42-47. Lewis et al concluded, "The present study found that within the range of self-reported mobile phone use there was no evidence for a relationship with semen quality."

What are the confounding factors on this study please.

Avendaño C, Mata A, Sanchez Sarmiento CA, Doncel GF.(2012). Use of laptop computers connected to internet through Wi-Fi decreases human sperm motility and increases sperm DNA fragmentation.Fertility Sterility. 97(1), 39-45.

FDA Answer to Follow-up question 3 part 3: The paper Avendano et al. examines the impact of radiofrequency radiation from an internet-connected laptop on human sperm in vitro. The authors test an interesting hypothesis with inventive methods. The experiment suffers from a lack of radiofrequency field homogeneity, inadequate information regarding occurrence of temperature change, ambiguity regarding if the control was handled the same as the exposed samples, and some of the semen samples were teratozoospermic which may have impacted the conclusions. The use of a reproducible source of RF exposure is essential to assure that reproduction of an experiment is possible. Cell phones, Wi-Fi routers, and laptops are not reproducible sources of RF exposure thus should not be used for experimentation.

This conclusion is consistent with recent expert reports on radiofrequency. For example, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015 concluded, "The previous SCENIHR Opinion concluded that there were no adverse effects on reproduction and development from RF fields at non-thermal exposure levels. The inclusion of more recent human and animal data does not change that assessment. Therefore, it is concluded that there is a strong overall weight of evidence against an effect of low-level RF fields on reproduction or development."[2]

My Follow Up Question 4. Is the FDA's stance to consider the SCENIHR opinion as the FDA's opinion?

FDA answer to Follow-Up Question 4: No, the SCENIHR expert working group is composed of expert scientists that have reviewed, reported on, and collated a large amount of information on RF radiation and FDA values their contribution. However, the FDA comes to its own conclusions.

My Follow Up Question 5. What review has the FDA done on fertility research. Please document and share this analysis.

Regarding your particular concern related to body weight, the NTP's draft report states, "Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation.[3]"

FDA Answer to Follow-Up Question 5: We follow the potential radiofrequency bioeffects literature. We are not actively engaged in laboratory or clinical fertility research. However, there may be other parts of the FDA that does research fertility.

My Follow Up Question 6. Please see on Page 8 the following:

- RESULTS
- In pregnant rats exposed to 900 MHz GSM- or CDMA-modulated RFR, no exposure-related effects were observed on the percent of dams littering, litter size, or sex distribution of pups.Small, exposure-level-dependent reductions (up to 7%) in body weights compared to controls were observed throughout gestation and lactation in dams exposed to GSM- or CDMA- modulated RFR. In the offspring, litter weights tended to be lower (up to 9%) in GSM and CDMA RFR-exposed groups compared to controls. Early in the lactation phase, body weights of male and female pups were lower in the GSM-modulated (8%) and CDMA-modulated (15%) RFR groups at 6 W/kg compared to controls. These weight differences in the offspring for both GSM and CDMA exposures tended to lessen (6% and 10%, respectively) as lactation progressed. Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation n in all groups of male rats exposed to GSM-modulated RFR

The quote you sent me is not adequate to address the concern I raised. As you can see from this paragraph, the weights were lower (see my yellow highlighted areas above) after prenatal exposure. You sent me details that pertain to the animals later in the study. (My daughter was a low birth weight when she was born and has caught up now.) The fact is that an effect of lower birth weight was found at non thermal levels. This indicates an important non thermal effect. (Smoking caused babies to be smaller as well and the industry stated this was good for mothers and doctors recommended that women smoke if they were gaining to much weight during

pregnancy.) Please explain why the FDA is not considering this effect and investigating the issue. Clearly non-thermal effects are evident from this study. Please explain the FDA's analysis on the issue of these lower body weights.

FDA Answer to Follow-up question 6: FDA is sorry that our quote was not adequate to address your concern. However, our quote is still accurate. The observation of a birth weight difference between exposed and control-animals is an important observation. The excerpted discussion above does say that pregnant rats gave birth to normal litters, pup were smaller early in lactation and lessened as lactation proceeded and no differences were noted in weight during the remainder of the chronic study. The very next paragraph discussed in the study said that control male rat survival was lower than RF exposed rat survival. This survival advantage for RF exposed male rats also may suggest that the lower birth weight at birth was not significant in the exposed group. We do not believe that this is a non-thermal effect of radiofrequency exposure. The study also said that thermal regulation was more difficult in pregnant or geriatric rats. It is possible that temperature elevation and thermal regulation was still an issue in these whole body irradiation experiments.

3.

Is it still the FDA's position that the weight of evidence does not show health effects? If so, please provide the documentation that supports this position by the FDA in light of the NTP results. In a prior email dated February 5, 2016 Email RE-Question about the FDA and radiofrequency radiation this is what you told me. Please provide the scientific research that shows safety.

The FDA's position has not changed. Based on the available scientific evidence, including published literature and published expert reports, the Agency has concluded that the current RF exposure limits provide adequate protection for use of RF consumer communication electronic products like cell phones.

My Follow Up Question 7. Please send me the "the available scientific evidence, including published literature and published expert reports" the FDA specifically looked at to state that "the Agency has concluded that the current RF exposure limits"

FDA Answer to Follow-up question 7: Copyright infringement is a problem with this request. What you are asking for is already on line at the WHO website, SCENIHR website, in the bibliographies of the documents noted in our original response and through PubMed literature searches.

Many expert reports have been released that discuss the strengths and weaknesses of the published literature. There have also been formal analyses and reviews of published expert reports.

You cite two reviews but is this how the FDA investigates ? by citing two reviews well cited by industry funded scientists? It is notable that this review "International and national expert group evaluations: biological/health effects of radiofrequency fields." not only cites industry linked reports but the authors state: "We thank Chung-Kwang Chou (chairman, SC-95 of the international committee on electromagnetic safety, Institute of Electrical and Electronic Engineers) for critical reading of the manuscript and helpful suggestions." CKChou is former Chief Motorola Scientist.

My Follow Up Question 8. Are these reviews that you refer to from organization that the FDA then is taking on as it's own opinion? How does the FDA determine that these reviews are scientifically sound and unduly influenced by industry?

FDA Answer to Follow-up Question 8: The FDA has been following RF exposure potential bioeffects since at least the early 1990s. We have met with and listened to numerous organizations on the topic, including your organization. The FDA reviews all published papers and reviews that are brought to our attention or that we identify through literature searches. Our answers were meant to guide you to scientific reviews that cover a large amount of literature in a systematic fashion. The expert review groups that have reviewed the RF literature have guidance policies and procedures in place to prevent undue influence from outside. FDA knows that Chung-Kwang Chou is an internationally recognized expert on RF radiation and we know that we also know that he

worked for industry. The weight of the evidence from the literature and expert opinions are what lead us to believe that the current exposure limits adequately protect the general public.

We note that Vershaeve 2012 specifically evaluated expert reports to assess bias. Verschaeve says, "**Evaluation of expert group reports based on 10 criteria**

An evaluation of the different reports should take into account a great number of aspects. Amongst them the composition of the working group, the topics that were taken into account and the methods that were used are certainly some of the important aspects. We therefore tried to identify the members or participants in the working group activities and tried to see whether they constituted a *multidisciplinary* and *independent* group of experts. Did they evaluate all scientific (peer reviewed) publications, or did they make a selection of papers, and if so, what was the rationale for doing so? Was this satisfactory? Was the report a consensus report? Where minority opinions mentioned?" Similarly, Vijayalaxmi and Scarfi 2014 included comments on negative and positive aspects of the expert groups and their reports.

4. Does the FDA consider oxidative stress a health effect? I sent you a review article last year about this and it seems important to share with the American people
(http://nebula.wsimg.com/107f00a88ae36803a132e3ca6c222157?AccessKeyId=045114F8E0676B9465FB&disposition=0&alloworigin=1**)**

Thank you for the review article on oxidative stress. We have reviewed it, and it contains opinions that have added to our understanding of the topic.

In the World Health Organization (WHO) International Agency for Research on Cancer (IARC) monograph 102 (2013), the IARC expert working group concluded that there was only weak evidence that adverse health effects could be caused by RF due to oxidative stress. We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects.

My Follow Up Question 9. How do you substantiate such a statement ?

"We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects."

FDA Answer to Follow-up Question 9: From the totality of the scientific literature available and expert opinions.

My Follow Up Question 10. Does the FDA think that oxidative stress can impact health.

the research study here states that constant oxidative stress over tome can lead to health problems. Please review and explain why this has not impacted the view of the FDA.

FDA Answer to Follow-up question 10: Oxidation is a normal component of metabolism and cells have redundant systems to deal with the consequences of oxidative stress. We are aware that approximately 70% of the damage done by ionizing radiation is due to oxidative stress. We follow the RF literature on potential mechanisms of action. Our opinion at this time is that the totality of the scientific literature does not support that hazardous levels of oxidative stress can be induced by radiofrequency radiation exposure that does not also cause hazardous temperature elevation.

5.

If the FDA is supposed to protect the public then they need to inform the public of the fine print instructions the manual related to RF. Why is the FDA not acting on this and informing people of the fine print instructions on RF on cell phones and wireless devices? Children are carrying phones on their bodies, tucked in spandex pants and in bras and jeans in school classrooms. Can you please explain why the FDA is not ensuring the public is aware of the fine print warnings?

There is a large safety factor included in the public exposure limit (see IEEE Std. C95.1-2005 Annex C, *Rationale*, for more information regarding this safety factor).

My Follow Up Question 11. What does the FDA think the safety factor is for SAR exposure limits. Please state it.

FDA Answer to Follow-Up Question 11: Wireless communication devices are required to meet radiofrequency (RF) energy exposure guidelines set forth by the Federal Communication Commission (FCC). These guidelines were last revised on August 1st, 1996 when the FCC adopted local body RF energy specific absorption rate (SAR) limits for devices operating within close proximity to the body as recommended by ANSI/IEEE C95.1-1992 guideline. The ANSI/IEEE C95.1 guidelines are based on protection from thermal effects of whole body RF energy exposure. RF exposure in the 1– 4W/kg SAR range was shown to induce behavioral changes in several animal species, including non-human primates. The observed behavioral change was accompanied by an increase in core temperature of ~1°C. ANSI/IEEE C95.1-1992 guideline derives the local body exposure limit in two steps. First the threshold for behavioral responses was set at 4W/kg SAR, and then a safety factor of 10 was put in place for exposure under controlled environmental conditions (occupational exposure). An additional safety factor of 5 was put in place for the general public exposure setting the whole body exposure limit at 0.08 W/kg. Thus the public whole body exposure limit is approximately 50 times lower than the threshold for heat related adverse health effects. Based on the general public whole body exposure limit a spatial peak limit on 1.6 W/kg averaged over one gram of tissue was set for local body exposure. Before adopting the ANSI/IEEE C95.1-1992 limits the FCC consulted with the Food and Drug Administration (FDA) and other health agencies.

We note that Federal Communications Commission (FCC) guidance on general RF exposure procedures and equipment authorization policies for mobile and portable devices explains that for devices designed to operate in contact with the body, the specific absorption rate (SAR) compliance tests should be conducted a separation distance of 5 mm or less (FCC KDB 447498 D01 section 4.2.2).

My Follow Up Question 12. Why does the FDA not share this information with the public? Why are these separation distances not stated on the FDA website so that te American people are aware of it. I have a teenage daughter and her friends do the following: They place the cell phone in their spandex pants against their skin. They lay the phone on their lap as they watch music videos or stream and facetime. They also sleep with the phone next to their head. They easily can roll over and sleep on the cell phone. Women carry cell phones in their bra all the time. The public is unaware. Again- Why does the FDA not share this information with the public on their website? So far it is a secret.

FDA Answer to Follow-up question 12: As you yourself noted, the FCC shares this information with the public. The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC.

Additionally, that FCC guidance explains that mobile and portable devices designed to be used with a body-worn accessory must be tested for body-worn accessory SAR compliance. According to the guidance, a conservative minimum test separation distance should be used for such testing, at worst case using no more than a 25 mm separation distance. The same FCC guidance states that operating manuals must include specific information to allow users to select body-worn accessories that meet the compliance test separation distance requirements, and all supported body-worn accessory operating configurations must be clearly disclosed to users, through conspicuous instructions in the user guide and user manual, to ensure unsupported operations are avoided.

My Follow Up Question 13. Everyone I have spoken to to is 100% unaware of this information buried in manuals. Please explain how the FDA has decided it is not their responsibility to inform the public on this. Has the FDA done a survey?

FDA Answer to Follow-up Question 13: The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC. As any web search for "usability of user manuals" will reveal, there is a lot of concern and research on

why most consumers ignore manuals and instructions. So it is not surprising that consumers are unaware of one particular fact in a manual when most consumers don't read anything in user manuals. The FDA has not done a survey and we are not aware if the FCC has.

Additionally, cell phone RF exposure compliance testing must be determined at the maximum average power level.

My Follow Up Question 14. Well actually you will use your cell phone at maximum power under several conditions such as if you are far from a tower with lower bars- or in an elevator, in a moving car far from a tower and video streaming- as you are aware. So it is possible. Is the FDA saying that although it is possible to be at maximum power, it is not necessary for the public to be aware because it does not happen often? There are many moments when people use phones in maximum power conditions- especially when they have a lot of applications on at once far from a base station. Please explain why the FDA is rationalizing not telling people about this.

FDA Answer to Follow-up Question 14: As you state, these are *moments* when a cell phone needs to operate at maximum power. Cell phones will always attempt to operate at the minimum power necessary in order to prolong battery life. Over the course of a day the average exposure is considerably lower. You mention using a cell phone in a moving car far from a tower; because of factors unrelated to RF exposure this is indeed a dangerous situation. The safety factors set in place for RF exposure adequately protect the general public.

However, the National Safety Council estimates cell phone use to be involved in 26 percent of all motor vehicle crashes – 5 percent of crashes involve texting, while 21 percent involve drivers talking on handheld or hands-free cell phones. (http://www.nsc.org/NewsDocuments/2014-Press-Release-Archive/3-25-2014-Injury-Facts-release.pdf) Clearly the greatest risk to public safety posed by cell phones is the risk of death or injury resulting from vehicular accidents due to distracted driving.

In order to conserve battery life, cell phones seldom actually operate at maximum power, which reduces the SAR proportionately.

My Follow Up Question 15. Can you tell me what data you have on how "cell phones seldom actually operate at maximum power" How often do they opeate at maximum power.

FDA Answer to Follow-Up Question 15: There has been considerable research on cell phone power consumption related to energy management and battery life. Actually transmitted RF power can be a minor part of the power consumption in smartphones which use a lot of power for the processor and display. Unfortunately these research efforts consider total transmit power over one battery charge and do not look at a typical time history of transmission power. Actual transmit power will be dependent on many factors unique to individuals, such as: where they live and work in relation to cell phone towers and usage patterns.

There is some relevant information in IARC Monograph 102 at the bottom of page 76 and top of page 77. There are also papers regarding exposure assessments that attempt to quantify dose for use in epidemiology assessments.

6.

I understand that the RFIAWG was given a presentation of these findings. What is the FDA perspective on the findings now that you have reviewed them please? Please detail the next steps for the FDA with a timeline.

The U.S. Radiofrequency Interagency Working Group (RFIAWG) has not had a presentation on findings from the NTP study.

My Follow Up Question 16. Why hasn't the U.S. Radiofrequency Interagency Working Group (RFIAWG) had a presentation on these findings? I thought the Groups role was to provide some sort of oversight? Why are they

not given a full presentation?

FDA Answer to Follow-up Question 16: The RFIAWG allows staff to discuss RF research and any concerns. It does not have a management or oversight role. The remainder of this question has already been answered. No further information is available.

My Follow Up Question 17. Has the FDA been given a presentation on the NTP findings of increased brain cancer, increased heart nerve sheath tumors and genotoxicity?

FDA Answer to Follow-up Question 17: The FDA has been briefed on the partial findings of the NTP study.

FDA's conclusion that current RF exposure limits adequately protect the public health has not changed based on the information in the draft NTP report about a portion of NTP's study.

My Follow Up Question 18. How did you determine that conclusion? What is the rationale for FDA's conclusions?

FDA Answer to Follow-up Question 18: From the totality of the scientific literature available and expert opinions.

When NTP completes its analysis and a full report is available, we will review it and consider what, if any, effect it has on the agency's thinking regarding risks associated with RF exposure from cell phones.

My Follow Up Question 19. Can you please explain the review process for the FDA and the transparency that will be involved in the review.

FDA Answer to Question 19: The NTP has briefed FDA on the partial result already. We believe that the NTP will also brief FDA on the completed total study when it is complete. FDA will review the entire study and decide if the results impact our understanding of its impact on RF safety.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue. What questions are being asked and of whom? What other FDA staff are involved in the process. Are any consultants working with the FDA? Who are they?

The Center for Devices and Radiological Health (CDRH) is the FDA center that regulates electronic products under the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act. Note: EPRC may also be referred to as "Radiological Health." Questions or concerns can be sent to the FDA document mail center:

U.S. Food & Drug Administration

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

10903 New Hampshire Avenue

WO66-5521

Silver Spring, MD 20993-0002

Marking the documents, "Attn: Division of Radiological Health" can help expedite routing to the Division of Radiological Health for review and appropriate follow-up. The staff in other divisions and offices who have the required expertise to answer specific questions are called upon for assistance when a need occurs. If necessary, we could call on expertise from other government (international, national, state, etc.) agencies, concerned consumer groups, or industry.

My Follow Up Question 20. You did not answer my questions so here they are again.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue?

What questions are being asked and of whom?

What other FDA staff are involved in the process.

Are any consultants working with the FDA? If so- Who are they?

FDA Answer to Question 20: These questions have been asked and answered.

8. The NTP study found DNA damage in the brain; please detail the FDA response to these findings and the next steps in terms of protecting the people.

We assume your question is referring to the draft supplemental NTP document that covers experiments looking for DNA damage. Our conclusion that current RF exposure limits adequately protect the public health has not changed based on our review of the draft NTP supplemental papers.

The NTP comet assay, indicated DNA damage (see the table).

My Follow Up Question 21. Please explain how this DNA damage found in the comet assay - not change the FDA opinion?

FDA Answer to Follow-up Question 21: The table you included is a variant of the table the NTP used in its briefings and is a summary of all of the Comet assay data. FDA does not agree with this summary table and how it reflects the data. Unfortunately, this paper has not been published and FDA is not at liberty to discuss the data further.

My Follow Up Question 22. What would change the FDA opinion? How much evidence is necessary?

FDA Answer to Follow-up Question 22: FDA believes that the current exposure standard is adequate to protect public health. In order to change that belief we would need to see well controlled studies that have reproducible results, we would also consider opinions from other expert organizations and the rational for or against changes by standard setting organizations that collectively say that the current exposure standards need to change to protect people.

9. Is the FDA preparing a response to inform the FCC of the official recommendations to the issue of cell phones and wireless? Please give specifics on the timelines.

As a general policy, the FDA does not comment on pending matters that are under review. If FDA had concerns regarding the current RF exposure limits, the agency would communicate those concerns to FCC.

My Follow Up Question 23. I thought that a transparent process was underway and that all comments would be available. The FCC states they are looking to their federal partners for guidance as they are not a health and safety agency. If the FDA does not give any comments then I wonder who will. Will the FDA be commenting at all to the FCC in their Proceeding Number 13-84? Have they ever commented?

FDA Answer to Follow-up Question 23: Question was asked and answered.

10.

The FDA has received reports of people who develop headaches, nerve damage and rashes from cell phone and wireless use. What is being done by the FDA to monitor these side effects?

The FDA has received anecdotal reports from individuals that attribute their symptoms to RF exposure from cordless phones and cell phones. The anecdotal reports are reviewed to determine if they contain new information indicating that RF radiation from an electronic product caused the adverse health effects described. No such evidence has been revealed through our review of those reports. We also monitor literature regarding experiments intended to prove or disprove a causal link between RF exposure and adverse health effects as well as literature regarding the most effective treatments for individuals suffering from these symptoms.

Where can these reports be accessed online?

Currently, these reports cannot be publicly accessed online.

My Follow Up Question 24. Why not, Can you please make them available.

FDA Answer to Follow-up Question 24: These records can contain patient specific medical information that we cannot make public. Redacted copies are probably available via Freedom of Information requests.

My Follow Up Question 25. Are you keeping track? Can you please make publicly available the amount of complaints that you have received

FDA Answer to Follow-up Question 25: The FDA does keep track. We can look into making the amount of complaints publically available.

What is the timeline for response to these concerns and reports?

The agency reviews these reports within one month. We only contact the responder if further information or clarification appears to be needed.

My Follow Up Question 26. Then what do you do with the information?

What is the procedure for reporting and what reports are the FDA generating on the issue?

To report a problem that appears to be related to electronic product radiation, please see our website at: https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ *ReportaProblem/default.htm*. FDA has not generated a report on reports it has received from individuals attributing their symptoms to RF exposure from consumer communications products.

FDA Answer to Follow-Up Question 26: An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product. The reports are required from manufacturers if the regulatory definition and criteria for requiring a report are met. Reports can come from consumers or occupational product user. The FDA reviews the reports to determine if the information indicates a defect could be present in a specific product or generally in a product type. To complete that evaluation we occasionally find we need to request more information from the manufacturer, report submitter or other relevant source.is necessary. For this product area the literature indicates that RF exposure is not a plausible cause of the problem described.

My Follow Up Question 27. Can you please generate an annual report on this. It seems important.

FDA Answer to Question 27: The FDA has not generated annual reports on cell phone complaints.

11. Will the FDA be recommending that the NTP now do a systematic review of radiofrequency considering the research results? If so when? If not, please explain why not-considering the widespread proliferation of cell phones. Please see where the FDA can nominate this issue for systematic review here – The NTP Office of Health Assessment and Translation (OHAT) develops literature-based evaluations to reach conclusions about potential human health hazards and to examine the state of the science. https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html**.**

We have not asked NTP to perform a systematic review for several reasons, including the fact that there are already numerous high quality expert reports, formal reviews, and meta-analyses related to the safety of use of RF consumer communication products.

My Follow Up Question 28. Please list those you are referring to. As far as I know, there are no systematic reviews that have been done and the US has not looked at this for over 20 years.

FDA Answer to Follow-Up Question 28: The IEEE International Committee on Electromagnetic Safety has posted a list of statements from governments and expert panels concerning research and conclusions about the possibility of health effects and safe exposure levels of radiofrequency energy. Many of these organizations have further analysis at their own web sites. Many of these organizations go into great detail on their analysis and have extensive bibliographies. The link to the IEEE website is attached. http://www.ices-emfsafety.org/expert-reviews/

In addition, the WHO EMF Project is currently updating the relevant Environmental Health Criteria.

My Follow Up Question 29: The WHO EMF Project was started with industry funded and is lead by an engineer and the group members are also connected to ICNIRP. It is not the same as the IARC. Is the FDA going to go with the results of the WHO EMF Project Environmental Health Criteria rather than do an independent review?

FDA Answer to Follow-up Question 29: FDA has answered this concern above. We have worked closely with the US National Academy of Science and we follow the work of expert review groups like IARC, the WHO EMF project, ICNIRP and SCENIHR. All of these expert review organizations have vetting processes for their expert scientific review panels. In addition, our scientists have been following the RF science at national and international meetings as well as via Pubmed since at least the early 1990s.

Thank you for the link. FDA has no plan to nominate this issue for systematic review at the NTP Office of Health Assessment and Translation at this time.

My Follow Up Question 30: Why not? . Please I would think a systematic review is in order considering the exposure to babies and children for a lifetime.

FDA Answer to Follow-up Question 30: There is no need for NTP to do this work for the FDA. This can be done by the FDA if necessary. Also, there are already many systematic reviews available.

Additional Questions:

My Follow Up Question 31.

Children are handed wireless laptops in classrooms across the USA. Please explain why the FDA is not informing the parents that many laptops have minimum separation distance of 20cm or 8 inches that the device should be from the body to ensure FCC compliance. The FDA should be informing the public about this distance. Why aren't they.

See this http://news.arubanetworks.com/press-release/prince-georges-county-public-schools-creates-one-nations-largest-k-12-wi-fi-deployment

FDA Answer to Follow-up Question 31: The antenna in laptop computers is usually located along the top edge of monitor of the laptop. Opening the laptop to use it puts the antenna approximately 8-10 inches away from the viewer. Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 32.

What proof of safety is there that pregnant women are protected when it comes to this radiation. They are placing laptops on their bellies. Has the FDA looked at research on impacts on pregnancy? If so, please share what studies have been reviewed.

FDA Answer to Follow-Up Question 32: The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) section 3.6.4.1 Reproductive Effects is also a good place to start a review.

My Follow Up Question 33.

Send me documentation that children adequately covered by the current US guidelines. Children absorb the radiation deeper into their brain and body. Please explain why the FDA states "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."

Why does the FDA clarify that long term effects are still being researched and children are more vulnerable to this radiation? They will have more impacts as they will have a lifetime of exposure. Why doesn't the FDA state this clearly for parents?

FDA Answer to Follow-Up Question 33: Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women. The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) is also a good place to get a compilation of published reports.

My Follow Up Question 34.

The FDA has outdated information (highlighting Interphone 2010 results) on a webpage under the cellphones section entitled Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors."

https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm212273.htm

FDA Senior staff have been asked to update these webpages 4 times over the last two years *and have not done so*. Please explain why this outdated material is being left on the FDA website.

FDA Answer to Follow-up Question 34: Thank you for your review of the FDA website on this topic. Your concern regarding the information is noted. The information is still useful.

Daniel Kassiday

SME: Electronic Product Radiation Control

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

U.S. Food and Drug Administration

Tel: 301-796-5865

daniel.kassiday@fda.hhs.gov

From: theodorams <theodorams@aol.com>
To: CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: Fwd: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.
Date: Fri, Sep 8, 2017 10:19 am
Attachments: Screen Shot 2017-09-08 at 9.52.01 AM.png (917K), Screen Shot 2017-09-08 at 9.51.40 AM.png (401K), Screen Shot 2017-09-08 at 9.51.40 AM.png (401K)

Dear Ombudsban,
Please help me to receive an answer to my questions.
Thank you , Theodora Scarato

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: theodorams <theodorams@aol.com>; Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>
Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>; alonzo.washington <alonzo.washington@house.state.md.us>; alonzo <alonzo@alonzowashington.com>; jamie.raskin <jamie.raskin@senate.state.md.us>
Sent: Fri, Sep 8, 2017 10:18 am
Subject: Re: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

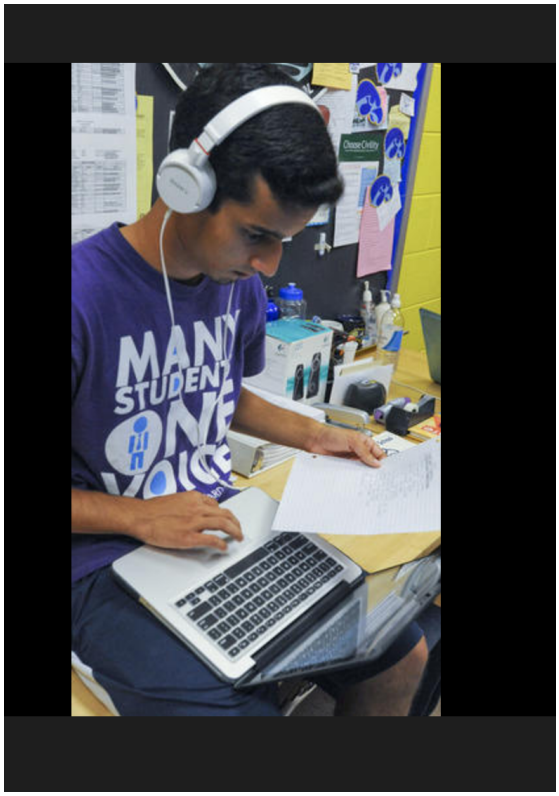
Dear Dr. Kassiday,

I have not received a response to the letter I sent Tue, Jun 13, 2017 9:09 am (see below this email the email I sent several months ago still unanswered).

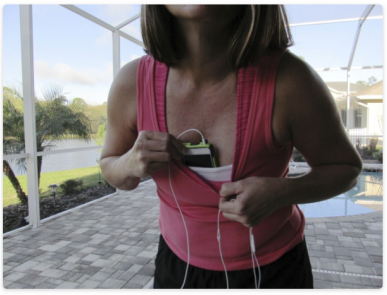
I will reiterate the questions and add a few more.

1. I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact. The FDA is aware that people use cell phones resting on their legs or on chests and therefore the FDA needs to be aware that the American public is being exposed to radiation levels exceeding our government guidelines. Please see this picture taken at an airport just this week. Note the laptop resting on this mans chest.

Please see these images from Maryland public Schools of students with devices on their body as well as how people typically wear their phones when they work out.


MANY
STUDENT
ONE
VOICE

iPhone slips into cami bra pocket easily.



Closer view of the layers and iPhone in pocket.

I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact in light of the fact that Americans are placing radiating cell phones and wireless devices directly on their bodies in violation of the FCC instructions and therefore exceeding FCC SAR values in their body.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that "it is OK" if this regulatory limit was exceeded because of this "large safety factor". Is that what you meant in your response?

3. So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." ?

4. And if the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor., *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? Could you please specify in terms of SAR as to the SAR at which the FDA will take action. For example is it a SAR of over 4w/kg or 7 w/kg or 21 w/kg? or more?

5. What is theSAR limit at which time the public will be informed by the FDA that cell phones violate US regulatory SAR limits?

6. I am included a chart so that you can see the cell phone, make and model and the SAR amount documenting how each phone violates SAR limits. Please see the document on this webpage but please note that the 0mm SAR listed is per the European 10 gram averaging. Therefore the equivalent US FCC 1 gram averaging SAR is likely over 2 times the amount listed here.

7. I want to make you aware that Dr. Marc Arazi came to the United States and presented a lecture on these SAR violations. Please watch the lecture here. https://ehtrust.org/cell-phones-violate-radiation-limits-doctor-calls-urgent-action-update-cell-phone-radiation-tests/ . I would like to ask if the FDA had watched this lecture?

8. I continue to ask that the FDA update the out of date webpages. Please update these webpages. Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors." Why is the FDA stil posting updated information?

Thank you so much. I would appreciate an answer to these questions. I am ccing my elected officials who are also interested in the answer to these questions.

Sincerely,
Theodora Scarato MSW

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>
Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Tue, Jun 13, 2017 9:09 am
Subject: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

Dear Dr. Kassiday,

I have attached below a press release regarding the data that the French government released testing data showing that cell phones violate cell phone radiation limits when tested directly against the body.

This information from France is clear evidence that cell phone testing is inadequate to protect consumers from the radiation limits for cell phones we have in place. Children and pregnant women place these phones directly on their bodies, store them in bras took them into spandex pants and all of these positions are not tested by the manufacturers.

1. I am writing to ask what the FDA's response is to this information just released from France showing violations of SAR when phones are tested at body contact.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that it is OK if this regulatory limit was exceeded because of this "large safety factor". So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." And if so, *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? (SAR 4w/kg or 7 w/kg or 21 w/kg? or more?). What is the FDA limit at which time the public will be informed? Clearly most people use phones on their body and teens sleep with phones on their chests. Please respond to each question in this paragraph.

I appreciate your response in advance.

Thank you very much,
Theodora Scarato

See press release on French data and prior communications below.

Cell Phone Radiation Scandal: More Exposure Than Manufacturers Claim

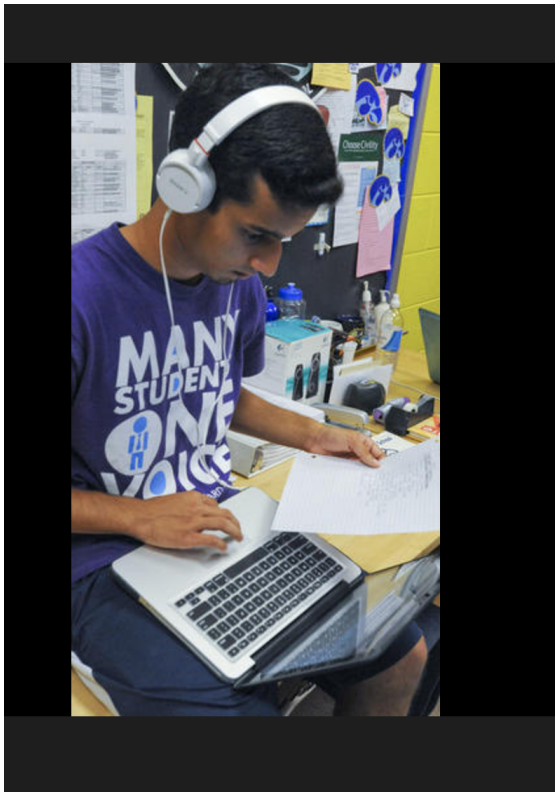
"PhoneGate" French government data reveals 9 out of 10 phones tested exceed regulatory limits

(Washington, DC) Under court order, the National Frequency Agency (ANFR) of France has just disclosed that most cell phones exceed government radiation limits when tested the way they

are used, next to the body. Manufacturers are not required to test phones in shirt or pants pockets. French government tests on hundreds of cell phones reveal that in 2015, 9 out of 10 phones exceed the manufacturer's reported radiation test levels when re-tested in positions where the phone is in contact with the body. The government had refused to disclose these test results until the court order.

Children handed cell phones as toys.

On June 1, 2017, ANFR

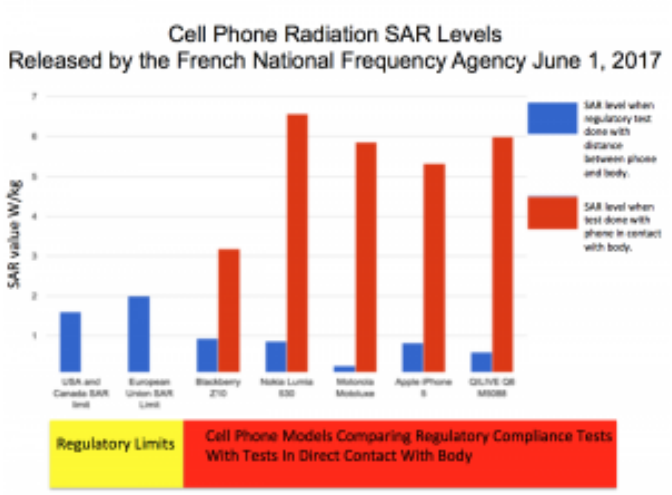


posted the details of the make, model and test results for each phone that was tested, after months of legal action by French physician Dr. Marc Arazi. Arazi's request for the information was initially denied. Popular brands such as Apple, Motorola, Samsung and Nokia were among the cell phone models tested. When tested in contact with the body, some phones have test results as high as triple the manufacturer's previously reported radiation levels.
"As a physician, I am deeply concerned about what this means for our health and especially the health of our children. People have a right to know that when cell phones are tested in ways people commonly use phones – such as in direct contact with their body – the values exceed current regulatory limits. This is a first victory for transparency in this industry scandal," commented Arazi.

Ricocheting in headlines throughout France, Arazi and his colleagues have coined the situation as "PhoneGate" because of the parallels to "Diesel Gate" – the Volkswagen emissions saga. Devra Davis, PhD, President of Environmental Health Trust explained, "Volkswagen cars passed diesel emission tests when tested in laboratory conditions, but when the cars were driven on real roads, they emitted far more fumes. In the same way, every one of these cell phones 'passed' laboratory radiation SAR tests. These phones are legally considered compliant. However, when these phones are tested in the ways that people actually use them in real life, such as in your jeans pocket or bra, the amount of absorbed radiation emissions in our bodies violates the regulatory limits."

"This is an enormous international scandal. This is not only about France and Europe, as this applies to all persons who use cell phones in every country. If phones were tested in the ways

we use them, they would be illegal," stated Dr. Davis, pointing out that these findings were replicated earlier by a US FCC certified laboratory as part of an investigation by the Canadian Broadcasting Corporation. Findings of higher radiation levels than expected (and even higher after phones are fixed) were also documented by the Holon Institute of Technology in Israel and featured on Israeli news.



"Far more concerning is that the regulatory limits do not protect the public from adverse health effects related to long-term exposures," Davis commented, pointing to recently published research. A study in the American Journal of Epidemiology found cell phones associated with a doubled risk of glioma, a type of brain cancer. Studies performed by the US National Toxicology Program found glioma and DNA damage increased in rats exposed to long-term cell phone radiation.

"I see children cradling cell phones in their laps as their mothers do grocery shopping. Teenagers are sleeping with cell phones placed on their chest or directly beside their heads all night long. Pregnant women put cell phones and wireless devices on their abdomen. Parents have a right to know that when children use cell phones in these ways, their bodies are absorbing wireless radiation at levels that exceed limits set for adults 20 years ago," stated Theodora Scarato, Program Director at Environmental Health Trust, referring to how the American Academy of Pediatrics has repeatedly called on the US Government to update cell phone testing to reflect current use patterns. The American Academy of Pediatrics has issued clear recommendations to reduce cell phone radiation exposures to children.

The Public is Unaware

France's National Agency of Health Security of Food, Environment and Labour (ANSES) July 2016 report "Radiofrequency Exposure and the Health of Children" conceded that the public is largely unaware of instructions to keep a distance between cell phones and anyone's head and body. ANSES stated that it was "unlikely that people, especially children, are aware of the conditions of use close to the body, as defined by manufacturers."

The Canadian Broadcasting Corporation (CBC) independent survey of more than 11,000 Canadians found that more than 80 percent were unaware of manufacturers' recommended separation distance and 67 percent admitted they carry their phones against their bodies.

The newly released French data is also corroborated by the 2017 independently commissioned investigation by the Canadian Broadcasting Corporation that tested popular cell phones in a US government certified testing laboratory and found SAR values surpassed the US and Canadian allowable SAR values when the phones were tested in body contact positions. In response to the CBC report, manufacturers stated they were fully compliant.

The Wireless Industry Argues "No Evidence" To Update Testing Protocols

Read what Apple states here -and you can see in example of how the SAR looks different depending on the tissue averaging at this

link https://www.apple.com/legal/rfexposure/iphone5,1/en/

The CTIA, the wireless industry lobby group is opposed to mandatory disclosures about the manufacturer's instructions and also is opposed to updating cell phone radiation testing methods to include body contact positions ***such as were performed by the French government.*** The CTIA argued that "there is no reliable evidence proving that current testing protocols fail to ensure compliance with RF standards, " in their submission to the US Federal Communications Commission concerning the FCC Docket on Human Exposures to Radiofrequency Radiation. The CTIA stated that "a zero-measuring requirement would not accurately mimic real usage or increase safety."

In California, the City of Berkeley was sued by the CTIA, a wireless industry lobby group, when the City passed an ordinance mandating consumers are informed of these manufacturers' instructions by retail stores. The CTIA argued that the "Right To Know Ordinance" violated free speech rights and recently lost their case in court when the judges ruled that the Ordinance was "in the public interest".

After litigation by UC Berkeley public health professor Dr. Joel Moskowitz, the California Department of Public Health (CDPH) released cell phone guidance that the Department scientists had drafted, but withheld from publicly posting for seven years. The guidelines aimed inform the public from possible health impacts from cell phone radiation.

Litigation is moving forward involving more than a dozen people in the U.S. who claim their brain cancer is related to their cell phone use. In Italy, a recent court ruling recognized a link between cellphone use and brain tumors and granted lifetime compensation to a man who developed a brain tumor after 15 years of work related cell phone use.

"Why does the public have to sue to get this information?" Scarato asked. "And what about children in schools? The Maryland State Children's Environmental Health and Protection Advisory Council has recommended that schools reduce radiofrequency radiation exposures to children by installing wired networks rather than Wi-Fi, same as in Cyprus, France and Israel. Yet at the same time, schools are now allowing or even insisting children bring cell phones into classrooms. I am sure most of those children are carrying these phones from class to class in their pockets close to their body. They are not aware of the radiation exposures."

Specific Absorption Rate Testing

Before a cell phone model is permitted to go on the market for sale, its manufacturer performs Specific Absorption Rate (SAR) tests to evaluate the radiation levels. SAR values are expressed in terms of watts per kilogram (W/kg) and are intended to measure the amount of cell phone radiofrequency radiation absorbed by the body when using a wireless device. SAR tests are performed in laboratories by measuring the SAR in a test dummy filled with liquid. The European Union regulations allow a maximum of SAR 2.0 W/kg. The United States and Canada allow a maximum of SAR 1.6 W/kg. Every cell phone is rated with a specific SAR value, and many countries mandate that these SAR values be prominently displayed to consumers on cell phone packaging.

Current wireless device SAR compliance testing regulations allow manufacturers to put a separation distance (usually about 15 mm) between the phone and the test dummy. Cell phone manufacturers are not required to test cell phones for SARs in positions which mimic direct contact between the phone and the body.

ANSES reported the following findings: In 2015, 89 percent of tested cell phones had a SAR greater than the maximum limit value of 2 W/kg and 25 percent had a SAR greater than 4 W/kg.

See below the French government test data. It is in French so you can scroll to the right to see the column called "DAS tronc (au contact)" which refers to the testing done against the body at "contact" position.

This information is found online here and you can download a spreadsheet of the information.

Calls For Continued Policy Action

Since 2010, France law has ensured that SAR levels are placed prominently on cell phone packaging and the sale of cell phones was banned for young children. French legislation in 2015 included several new policies aimed at reducing exposure to radiofrequency radiation. Arazi called on the Health and Environment Ministers and Consumer Affairs and Fraud Prevention Agency to take immediate action on this new information by informing the public and issuing new protective policies.

Link to the French ANFR Website with full details on cell phones/make/model

ANFR Cell Phone SAR Measurements (PDF)

Link to France's National Agency of Health Security of Food, Environment and Labour Report on Radiofrequency and Children (In French)

English Translation of ANSES Report Section on Cell Phone Studies

NEWS REPORTS

Scandal about mobile radiation: Mobile Phones rays more than manufacturer's claim, Forskning.dk, June 7, 2017

Phones: Test bench or bench?, Journal of The Environment , June 7, 2017

Mobile phone: reassuring results that do not reassure everyone, Journal of Internal Medicine, Paris, June 7, 2017

Electromagnetic waves: Do mobile phones meet standards? Science Avenir, Paris France, June 7, 2017

France publishes the results of tests carried out on 379 GSM, Belgium News, June 3, 2017

Mobile phone: after the publication of ANFR data, Dr Marc Arazi points to irregularities, The Daily Health, June 2, 2017

Suspicions about Mobile Phones Le Monde , December 23, 2016

Phonegate: A first victory with the publication by the ANFR of the SAR, Press Release by French physician Marc Arazi, June 1, 2017

I apologize for the delay.

Your Follow up Questions To The FDA in blue

FDA answers to follow up questions are in red
I asked:Will the FDA be updating it's website to include the NTP study results on radiofrequency radiation?
The FDA answered:Our conclusion that current radiofrequency (RF) exposure limits adequately protect the public health has not changed based on the draft National Toxicology Program (NTP) report about a portion of NTP's study. We do not anticipate a website update on the NTP study before NTP publishes a final report regarding the complete study.
My Follow Up Question 1. : The results on the brain and heart cancers are final. They are not a draft In addition the research showing a genotoxic effect are now being added to the report. Even if all the other findings show "no effect" this is a significant finding. Why is the FDA waiting when children and pregnant women are actively exposing themselves to this radiation unaware that they could be racking up hours of exposure.

FDA answer to Follow-up Question 1: The results of the NTP study have not been published as a final document for the partial experiment discussed publically by the NTP nor have they been peer reviewed in the literature. Likewise, the genotoxicity experiments have also not been released publicly nor have they been peer reviewed. The data that has been released by the NTP is only a small subset of a much larger study. While the results add to the body of data on this topic they are not evidence that there is any risk of adverse health effects when exposures are at or below current exposure limits. When we have evidence of a public health hazard or significant risk, FDA has not hesitated to issue and disseminate appropriate safety notices. Our conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 2. Please explain how the FDA arrived at that conclusion?
FDA Answer to Follow-up Question 2: While the experiments are interesting and well performed, the results are not clear and conclusive when compared to whole body or partial body RF exposures that comply with the existing safety limits. The lowest whole body RF exposures tested in the NTP experiment are much higher than the allowable whole body exposure limit. There are differences between the experimental controls and the historical controls that further limit the conclusions reached. Our conclusion that the current RF exposure limits adequately protect the public health is not altered by the available information related to the NTP study.
Why is the FDA not considering the evidence showing fertility damage from wireless and cellphones? Specifically the research on impacts on sperm DNA at non thermal levels, impacts on the ovaries and the fact that the NTP study found the exposed group had offspring with lower birth weight. See research study found here in the drop down:http://ehtrust.org/science/research-on-wireless-health-effects/
We have looked at the papers you identified. Those studies suffer from many confounding factors that significantly limit or eliminate their impact. There is insufficient evidence available to establish adverse health effects, including when these studies are taken into account.
My Follow Up Question 3. So you are stating that all these studies are insufficient. On what grounds?
FDA Answer to Follow-up Question 3 part 1: Peer-reviewed papers are evaluated for any adverse effects reported to be caused by RF exposure. The relative strength of those papers' conclusions must be considered. Examples of factors that may weaken the utility of a paper include: the study design, study protocol violations, RF exposure sources, the dosimetric methods, SAR determination, thermometry, reproducibility of RF emissions, reproducibility of all environmental factors (temperature,

air flow, vibration, etc.), differences with historical controls and recall bias. Based on the individual papers and analysis by expert review panels we conclude that the current RF exposure limits adequately protect the public health. This includes reproductive health.

What do you think of this study please in particular as the majority of studies showed an effect.

Houston B., et al. "The effects of radiofrequency electromagnetic radiation on sperm function." Reproduction, 2016.

- Among a total of 27 studies investigating the effects of RF-EMR on the male reproductive system, negative consequences of exposure were reported in 21. Within these 21 studies, 11 of the 15 that investigated sperm motility reported significant declines, 7 of 7 that measured the production of reactive oxygen species documented elevated levels and 4 of 5 studies that probed for DNA damage highlighted increased damage, due to RF-EMR exposure. Associated with this, RF-EMR treatment reduced antioxidant levels in 6 of 6 studies that studied this phenomenon, while consequences of RF-EMR were successfully ameliorated with the supplementation of antioxidants in all 3 studies that carried out these experiments.

FDA Answer to Follow-up Question 3 part 2 – re: Houston et al: Thank you for directing us to the Houston et al. "The effects of radiofrequency electromagnetic radiation on sperm function" review paper. We find this scientific opinion of this review paper to be interesting and the tabulation of the available data from the cited references useful. The paper does not extensively cover the confounding factors present in the papers reviewed. This appears to be because it is a review article that's purpose is the development of a possible mechanism of action. The authors stated that, "we explored the documented impact of RF-EMR on the male reproductive system and considered any common observations that could provide insights on a potential mechanism". The authors also acknowledge that research to date is not conclusive. In their conclusion, they say, "to date, contradictory studies surrounding the impact of RF-EMR on biological systems maintain controversy over this subject". The review's authors' proposed two-step mechanism of action and their call for further laboratory research are interesting. While the opinion of the authors contributes to the body of knowledge on this topic it alone does not change the current understanding of mechanism of RF action nor does it prove there is an adverse effect of RF exposure that complies with the limits on male reproduction. The current RF exposure limit adequately protects the public health.

Additionally, a recent paper by Lewis adds some epidemiological evidence that there is no adverse effect from RF exposures from cell phones. Please see, Lewis, R. C., et al. (2017). "Self-reported mobile phone use and semen parameters among men from a fertility clinic." Reprod Toxicol 67: 42-47. Lewis et al concluded, "The present study found that within the range of self-reported mobile phone use there was no evidence for a relationship with semen quality."

What are the confounding factors on this study please.

Avendaño C, Mata A, Sanchez Sarmiento CA, Doncel GF.(2012). Use of laptop computers connected to internet through Wi-Fi decreases human sperm motility and increases sperm DNA fragmentation.Fertility Sterility. 97(1), 39-45.

FDA Answer to Follow-up question 3 part 3: The paper Avendano et al. examines the impact of radiofrequency radiation from an internet-connected laptop on human sperm in vitro. The authors test an interesting hypothesis with inventive methods. The experiment suffers from a lack of radiofrequency field homogeneity, inadequate information regarding occurrence of temperature change, ambiguity regarding if the control was handled the same as the exposed samples, and some

of the semen samples were teratozoospermic which may have impacted the conclusions. The use of a reproducible source of RF exposure is essential to assure that reproduction of an experiment is possible. Cell phones, Wi-Fi routers, and laptops are not reproducible sources of RF exposure thus should not be used for experimentation.

This conclusion is consistent with recent expert reports on radiofrequency. For example, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015 concluded, "The previous SCENIHR Opinion concluded that there were no adverse effects on reproduction and development from RF fields at non-thermal exposure levels. The inclusion of more recent human and animal data does not change that assessment. Therefore, it is concluded that there is a strong overall weight of evidence against an effect of low-level RF fields on reproduction or development."[2]

My Follow Up Question 4. Is the FDA's stance to consider the SCENIHR opinion as the FDA's opinion?

FDA answer to Follow-Up Question 4: No, the SCENIHR expert working group is composed of expert scientists that have reviewed, reported on, and collated a large amount of information on RF radiation and FDA values their contribution. However, the FDA comes to its own conclusions.

My Follow Up Question 5. What review has the FDA done on fertility research. Please document and share this analysis.

Regarding your particular concern related to body weight, the NTP's draft report states, "Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation.[3]"

FDA Answer to Follow-Up Question 5: We follow the potential radiofrequency bioeffects literature. We are not actively engaged in laboratory or clinical fertility research. However, there may be other parts of the FDA that does research fertility.

My Follow Up Question 6. Please see on Page 8 the following:

- RESULTS
- In pregnant rats exposed to 900 MHz GSM- or CDMA-modulated RFR, no exposure-related effects were observed on the percent of dams littering, litter size, or sex distribution of pups.Small, exposure-level-dependent reductions (up to 7%) in body weights compared to controls were observed throughout gestation and lactation in dams exposed to GSM- or CDMA-modulated RFR. In the offspring, litter weights tended to be lower (up to 9%) in GSM and CDMA RFR-exposed groups compared to controls. Early in the lactation phase, body weights of male and female pups were lower in the GSM-modulated (8%) and CDMA-modulated (15%) RFR groups at 6 W/kg compared to controls. These weight differences in the offspring for both GSM and CDMA exposures tended to lessen (6% and 10%, respectively) as lactation progressed. Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation n in all groups of male rats exposed to GSM-modulated RFR

The quote you sent me is not adequate to address the concern I raised. As you can see from this paragraph, the weights were lower (see my yellow highlighted areas above) after prenatal exposure. You sent me details that pertain to the animals later in the study. (My daughter was a low birth weight when she was born and has caught up now.) The fact is that an effect of lower birth weight was found at non thermal levels. This indicates an important non thermal effect. (Smoking caused babies to be smaller as well and the industry stated this was good for mothers and doctors recommended that women smoke if they were gaining to much weight during pregnancy.) Please explain why the FDA is

not considering this effect and investigating the issue. Clearly non- thermal effects are evident from this study. Please explain the FDA's analysis on the issue of these lower body weights.

FDA Answer to Follow-up question 6: FDA is sorry that our quote was not adequate to address your concern. However, our quote is still accurate. The observation of a birth weight difference between exposed and control-animals is an important observation. The excerpted discussion above does say that pregnant rats gave birth to normal litters, pup were smaller early in lactation and lessened as lactation proceeded and no differences were noted in weight during the remainder of the chronic study. The very next paragraph discussed in the study said that control male rat survival was lower than RF exposed rat survival. This survival advantage for RF exposed male rats also may suggest that the lower birth weight at birth was not significant in the exposed group. We do not believe that this is a non-thermal effect of radiofrequency exposure. The study also said that thermal regulation was more difficult in pregnant or geriatric rats. It is possible that temperature elevation and thermal regulation was still an issue in these whole body irradiation experiments.

3.

Is it still the FDA's position that the weight of evidence does not show health effects? If so, please provide the documentation that supports this position by the FDA in light of the NTP results. In a prior email dated February 5, 2016 Email RE-Question about the FDA and radiofrequency radiation this is what you told me. Please provide the scientific research that shows safety.

The FDA's position has not changed. Based on the available scientific evidence, including published literature and published expert reports, the Agency has concluded that the current RF exposure limits provide adequate protection for use of RF consumer communication electronic products like cell phones.

My Follow Up Question 7. Please send me the "the available scientific evidence, including published literature and published expert reports" the FDA specifically looked at to state that "the Agency has concluded that the current RF exposure limits"

FDA Answer to Follow-up question 7: Copyright infringement is a problem with this request. What you are asking for is already on line at the WHO website, SCENIHR website, in the bibliographies of the documents noted in our original response and through PubMed literature searches.

Many expert reports have been released that discuss the strengths and weaknesses of the published literature. There have also been formal analyses and reviews of published expert reports.

You cite two reviews but is this how the FDA investigates ? by citing two reviews well cited by industry funded scientists? It is notable that this review "International and national expert group evaluations: biological/health effects of radiofrequency fields." not only cites industry linked reports but the authors state: "We thank Chung-Kwang Chou (chairman, SC-95 of the international committee on electromagnetic safety, Institute of Electrical and Electronic Engineers) for critical reading of the manuscript and helpful suggestions." CKChou is former Chief Motorola Scientist.

My Follow Up Question 8. Are these reviews that you refer to from organization that the FDA then is taking on as it's own opinion? How does the FDA determine that these reviews are scientifically sound and unduly influenced by industry?

FDA Answer to Follow-up Question 8: The FDA has been following RF exposure potential bioeffects since at least the early 1990s. We have met with and listened to numerous organizations on the topic, including your organization. The FDA reviews all published papers and reviews that are brought to our attention or that we identify through literature searches. Our answers were meant to guide you to

scientific reviews that cover a large amount of literature in a systematic fashion. The expert review groups that have reviewed the RF literature have guidance policies and procedures in place to prevent undue influence from outside. FDA knows that Chung-Kwang Chou is an internationally recognized expert on RF radiation and we know that we also know that he worked for industry. The weight of the evidence from the literature and expert opinions are what lead us to believe that the current exposure limits adequately protect the general public.

We note that Vershaeve 2012 specifically evaluated expert reports to assess bias. Verschaeve says,

"Evaluation of expert group reports based on 10 criteria

An evaluation of the different reports should take into account a great number of aspects. Amongst them the composition of the working group, the topics that were taken into account and the methods that were used are certainly some of the important aspects. We therefore tried to identify the members or participants in the working group activities and tried to see whether they constituted a multidisciplinary and independent group of experts. Did they evaluate all scientific (peer reviewed) publications, or did they make a selection of papers, and if so, what was the rationale for doing so? Was this satisfactory? Was the report a consensus report? Where minority opinions mentioned?" Similarly, Vijayalaxmi and Scarfi 2014 included comments on negative and positive aspects of the expert groups and their reports.

4. Does the FDA consider oxidative stress a health effect? I sent you a review article last year about this and it seems important to share with the American people (http://nebula.wsimg.com/107f00a88ae36803a132e3ca6c222157?AccessKeyId=045114F8E0676B9465FB&disposition=0&alloworigin=1)

Thank you for the review article on oxidative stress. We have reviewed it, and it contains opinions that have added to our understanding of the topic.

In the World Health Organization (WHO) International Agency for Research on Cancer (IARC) monograph 102 (2013), the IARC expert working group concluded that there was only weak evidence that adverse health effects could be caused by RF due to oxidative stress. We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects.

My Follow Up Question 9. How do you substantiate such a statement ?

"We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects."

FDA Answer to Follow-up Question 9: From the totality of the scientific literature available and expert opinions.

My Follow Up Question 10. Does the FDA think that oxidative stress can impact health.

the research study here states that constant oxidative stress over tome can lead to health problems. Please review and explain why this has not impacted the view of the FDA.

FDA Answer to Follow-up question 10: Oxidation is a normal component of metabolism and cells have redundant systems to deal with the consequences of oxidative stress. We are aware that approximately 70% of the damage done by ionizing radiation is due to oxidative stress. We follow the RF literature on potential mechanisms of action. Our opinion at this time is that the totality of the scientific literature does not support that hazardous levels of oxidative stress can be induced by radiofrequency radiation exposure that does not also cause hazardous temperature elevation.

5.

If the FDA is supposed to protect the public then they need to inform the public of the fine print instructions the manual related to RF. Why is the FDA not acting on this and informing people of the fine print instructions on RF on cell phones and wireless devices? Children are carrying phones on

their bodies, tucked in spandex pants and in bras and jeans in school classrooms. Can you please explain why the FDA is not ensuring the public is aware of the fine print warnings?

There is a large safety factor included in the public exposure limit (see IEEE Std. C95.1-2005 Annex C, Rationale, for more information regarding this safety factor).

My Follow Up Question 11. What does the FDA think the safety factor is for SAR exposure limits. Please state it.

FDA Answer to Follow-Up Question 11: Wireless communication devices are required to meet radiofrequency (RF) energy exposure guidelines set forth by the Federal Communication Commission (FCC). These guidelines were last revised on August 1st, 1996 when the FCC adopted local body RF energy specific absorption rate (SAR) limits for devices operating within close proximity to the body as recommended by ANSI/IEEE C95.1-1992 guideline. The ANSI/IEEE C95.1 guidelines are based on protection from thermal effects of whole body RF energy exposure. RF exposure in the 1– 4W/kg SAR range was shown to induce behavioral changes in several animal species, including non-human primates. The observed behavioral change was accompanied by an increase in core temperature of ~1°C. ANSI/IEEE C95.1-1992 guideline derives the local body exposure limit in two steps. First the threshold for behavioral responses was set at 4W/kg SAR, and then a safety factor of 10 was put in place for exposure under controlled environmental conditions (occupational exposure). An additional safety factor of 5 was put in place for the general public exposure setting the whole body exposure limit at 0.08 W/kg. Thus the public whole body exposure limit is approximately 50 times lower than the threshold for heat related adverse health effects. Based on the general public whole body exposure limit a spatial peak limit on 1.6 W/kg averaged over one gram of tissue was set for local body exposure. Before adopting the ANSI/IEEE C95.1-1992 limits the FCC consulted with the Food and Drug Administration (FDA) and other health agencies.

We note that Federal Communications Commission (FCC) guidance on general RF exposure procedures and equipment authorization policies for mobile and portable devices explains that for devices designed to operate in contact with the body, the specific absorption rate (SAR) compliance tests should be conducted a separation distance of 5 mm or less (FCC KDB 447498 D01 section 4.2.2).

My Follow Up Question 12. Why does the FDA not share this information with the public? Why are these separation distances not stated on the FDA website so that te American people are aware of it. I have a teenage daughter and her friends do the following: They place the cell phone in their spandex pants against their skin. They lay the phone on their lap as they watch music videos or stream and facetime. They also sleep with the phone next to their head. They easily can roll over and sleep on the cell phone. Women carry cell phones in their bra all the time. The public is unaware. Again- Why does the FDA not share this information with the public on their website? So far it is a secret.

FDA Answer to Follow-up question 12: As you yourself noted, the FCC shares this information with the public. The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC.

Additionally, that FCC guidance explains that mobile and portable devices designed to be used with a body-worn accessory must be tested for body-worn accessory SAR compliance. According to the guidance, a conservative minimum test separation distance should be used for such testing, at worst case using no more than a 25 mm separation distance. The same FCC guidance states that operating manuals must include specific information to allow users to select body-worn accessories that meet

the compliance test separation distance requirements, and all supported body-worn accessory operating configurations must be clearly disclosed to users, through conspicuous instructions in the user guide and user manual, to ensure unsupported operations are avoided.

My Follow Up Question 13. Everyone I have spoken to to is 100% unaware of this information buried in manuals. Please explain how the FDA has decided it is not their responsibility to inform the public on this. Has the FDA done a survey?

FDA Answer to Follow-up Question 13: The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC. As any web search for "usability of user manuals" will reveal, there is a lot of concern and research on why most consumers ignore manuals and instructions. So it is not surprising that consumers are unaware of one particular fact in a manual when most consumers don't read anything in user manuals. The FDA has not done a survey and we are not aware if the FCC has. Additionally, cell phone RF exposure compliance testing must be determined at the maximum average power level.

My Follow Up Question 14. Well actually you will use your cell phone at maximum power under several conditions such as if you are far from a tower with lower bars- or in an elevator, in a moving car far from a tower and video streaming- as you are aware. So it is possible. Is the FDA saying that although it is possible to be at maximum power, it is not necessary for the public to be aware because it does not happen often? There are many moments when people use phones in maximum power conditions- especially when they have a lot of applications on at once far from a base station. Please explain why the FDA is rationalizing not telling people about this.

FDA Answer to Follow-up Question 14: As you state, these are moments when a cell phone needs to operate at maximum power. Cell phones will always attempt to operate at the minimum power necessary in order to prolong battery life. Over the course of a day the average exposure is considerably lower. You mention using a cell phone in a moving car far from a tower; because of factors unrelated to RF exposure this is indeed a dangerous situation. The safety factors set in place for RF exposure adequately protect the general public.

However, the National Safety Council estimates cell phone use to be involved in 26 percent of all motor vehicle crashes – 5 percent of crashes involve texting, while 21 percent involve drivers talking on handheld or hands-free cell phones. (http://www.nsc.org/NewsDocuments/2014-Press-Release-Archive/3-25-2014-Injury-Facts-release.pdf) Clearly the greatest risk to public safety posed by cell phones is the risk of death or injury resulting from vehicular accidents due to distracted driving.

In order to conserve battery life, cell phones seldom actually operate at maximum power, which reduces the SAR proportionately.

My Follow Up Question 15. Can you tell me what data you have on how "cell phones seldom actually operate at maximum power" How often do they opeate at maximum power.

FDA Answer to Follow-Up Question 15: There has been considerable research on cell phone power consumption related to energy management and battery life. Actually transmitted RF power can be a minor part of the power consumption in smartphones which use a lot of power for the processor and display. Unfortunately these research efforts consider total transmit power over one battery charge and do not look at a typical time history of transmission power. Actual transmit power will be dependent on many factors unique to individuals, such as: where they live and work in relation to cell phone towers and usage patterns.

There is some relevant information in IARC Monograph 102 at the bottom of page 76 and top of page 77. There are also papers regarding exposure assessments that attempt to quantify dose for use in epidemiology assessments.

6.

I understand that the RFIAWG was given a presentation of these findings. What is the FDA perspective on the findings now that you have reviewed them please? Please detail the next steps for the FDA with a timeline.

The U.S. Radiofrequency Interagency Working Group (RFIAWG) has not had a presentation on findings from the NTP study.

My Follow Up Question 16. Why hasn't the U.S. Radiofrequency Interagency Working Group (RFIAWG) had a presentation on these findings? I thought the Groups role was to provide some sort of oversight? Why are they not given a full presentation?

FDA Answer to Follow-up Question 16: The RFIAWG allows staff to discuss RF research and any concerns. It does not have a management or oversight role. The remainder of this question has already been answered. No further information is available.

My Follow Up Question 17. Has the FDA been given a presentation on the NTP findings of increased brain cancer, increased heart nerve sheath tumors and genotoxicity?

FDA Answer to Follow-up Question 17: The FDA has been briefed on the partial findings of the NTP study.

FDA's conclusion that current RF exposure limits adequately protect the public health has not changed based on the information in the draft NTP report about a portion of NTP's study.

My Follow Up Question 18. How did you determine that conclusion? What is the rationale for FDA's conclusions?

FDA Answer to Follow-up Question 18: From the totality of the scientific literature available and expert opinions.

When NTP completes its analysis and a full report is available, we will review it and consider what, if any, effect it has on the agency's thinking regarding risks associated with RF exposure from cell phones.

My Follow Up Question 19. Can you please explain the review process for the FDA and the transparency that will be involved in the review.

FDA Answer to Question 19: The NTP has briefed FDA on the partial result already. We believe that the NTP will also brief FDA on the completed total study when it is complete. FDA will review the entire study and decide if the results impact our understanding of its impact on RF safety.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue. What questions are being asked and of whom? What other FDA staff are involved in the process. Are any consultants working with the FDA? Who are they?

The Center for Devices and Radiological Health (CDRH) is the FDA center that regulates electronic products under the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act. Note: EPRC may also be referred to as "Radiological Health." Questions or concerns can be sent to the FDA document mail center:

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue

WO66-5521
Silver Spring, MD 20993-0002
Marking the documents, “Attn: Division of Radiological Health” can help expedite routing to the Division of Radiological Health for review and appropriate follow-up. The staff in other divisions and offices who have the required expertise to answer specific questions are called upon for assistance when a need occurs. If necessary, we could call on expertise from other government (international, national, state, etc.) agencies, concerned consumer groups, or industry.
My Follow Up Question 20. You did not answer my questions so here they are again.
Who is the point person at the FDA for this issue and what are they doing in regards to this issue?
What questions are being asked and of whom?
What other FDA staff are involved in the process.
Are any consultants working with the FDA? If so- Who are they?
FDA Answer to Question 20: These questions have been asked and answered.
8. The NTP study found DNA damage in the brain; please detail the FDA response to these findings and the next steps in terms of protecting the people.
We assume your question is referring to the draft supplemental NTP document that covers experiments looking for DNA damage. Our conclusion that current RF exposure limits adequately protect the public health has not changed based on our review of the draft NTP supplemental papers.

The NTP comet assay, indicated DNA damage (see the table).
My Follow Up Question 21. Please explain how this DNA damage found in the comet assay - not change the FDA opinion?
FDA Answer to Follow-up Question 21: The table you included is a variant of the table the NTP used in its briefings and is a summary of all of the Comet assay data. FDA does not agree with this summary table and how it reflects the data. Unfortunately, this paper has not been published and FDA is not at liberty to discuss the data further.
My Follow Up Question 22. What would change the FDA opinion? How much evidence is necessary?
FDA Answer to Follow-up Question 22: FDA believes that the current exposure standard is adequate to protect public health. In order to change that belief we would need to see well controlled studies that have reproducible results, we would also consider opinions from other expert organizations and the rational for or against changes by standard setting organizations that collectively say that the current exposure standards need to change to protect people.
9. Is the FDA preparing a response to inform the FCC of the official recommendations to the issue of cell phones and wireless? Please give specifics on the timelines.
As a general policy, the FDA does not comment on pending matters that are under review. If FDA had concerns regarding the current RF exposure limits, the agency would communicate those concerns to FCC.
My Follow Up Question 23. I thought that a transparent process was underway and that all comments would be available. The FCC states they are looking to their federal partners for guidance as they are not a health and safety agency. If the FDA does not give any comments then I wonder who will. Will the FDA be commenting at all to the FCC in their Proceeding Number 13-84? Have they ever commented?
FDA Answer to Follow-up Question 23: Question was asked and answered.
10.

The FDA has received reports of people who develop headaches, nerve damage and rashes from cell phone and wireless use. What is being done by the FDA to monitor these side effects?
The FDA has received anecdotal reports from individuals that attribute their symptoms to RF exposure from cordless phones and cell phones. The anecdotal reports are reviewed to determine if they contain new information indicating that RF radiation from an electronic product caused the adverse health effects described. No such evidence has been revealed through our review of those reports. We also monitor literature regarding experiments intended to prove or disprove a causal link between RF exposure and adverse health effects as well as literature regarding the most effective treatments for individuals suffering from these symptoms.
Where can these reports be accessed online?
Currently, these reports cannot be publicly accessed online.
My Follow Up Question 24. Why not, Can you please make them available.
FDA Answer to Follow-up Question 24: These records can contain patient specific medical information that we cannot make public. Redacted copies are probably available via Freedom of Information requests.
My Follow Up Question 25. Are you keeping track? Can you please make publicly available the amount of complaints that you have received
FDA Answer to Follow-up Question 25: The FDA does keep track. We can look into making the amount of complaints publically available.
What is the timeline for response to these concerns and reports?
The agency reviews these reports within one month. We only contact the responder if further information or clarification appears to be needed.
My Follow Up Question 26. Then what do you do with the information?
What is the procedure for reporting and what reports are the FDA generating on the issue?
To report a problem that appears to be related to electronic product radiation, please see our website at: https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ ReportaProblem/default.htm. FDA has not generated a report on reports it has received from individuals attributing their symptoms to RF exposure from consumer communications products.
FDA Answer to Follow-Up Question 26: An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product. The reports are required from manufacturers if the regulatory definition and criteria for requiring a report are met. Reports can come from consumers or occupational product user. The FDA reviews the reports to determine if the information indicates a defect could be present in a specific product or generally in a product type. To complete that evaluation we occasionally find we need to request more information from the manufacturer, report submitter or other relevant source.is necessary. For this product area the literature indicates that RF exposure is not a plausible cause of the problem described.
My Follow Up Question 27. Can you please generate an annual report on this. It seems important.
FDA Answer to Question 27: The FDA has not generated annual reports on cell phone complaints.
11. Will the FDA be recommending that the NTP now do a systematic review of radiofrequency considering the research results? If so when? If not, please explain why not-considering the widespread proliferation of cell phones. Please see where the FDA can nominate this issue for systematic review here – The NTP Office of Health Assessment and Translation (OHAT) develops

literature-based evaluations to reach conclusions about potential human health hazards and to examine the state of the science. https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html.

We have not asked NTP to perform a systematic review for several reasons, including the fact that there are already numerous high quality expert reports, formal reviews, and meta-analyses related to the safety of use of RF consumer communication products.

My Follow Up Question 28. Please list those you are referring to. As far as I know, there are no systematic reviews that have been done and the US has not looked at this for over 20 years.

FDA Answer to Follow-Up Question 28: The IEEE International Committee on Electromagnetic Safety has posted a list of statements from governments and expert panels concerning research and conclusions about the possibility of health effects and safe exposure levels of radiofrequency energy. Many of these organizations have further analysis at their own web sites. Many of these organizations go into great detail on their analysis and have extensive bibliographies. The link to the IEEE website is attached. http://www.ices-emfsafety.org/expert-reviews/

In addition, the WHO EMF Project is currently updating the relevant Environmental Health Criteria.

My Follow Up Question 29: The WHO EMF Project was started with industry funded and is lead by an engineer and the group members are also connected to ICNIRP. It is not the same as the IARC. Is the FDA going to go with the results of the WHO EMF Project Environmental Health Criteria rather than do an independent review?

FDA Answer to Follow-up Question 29: FDA has answered this concern above. We have worked closely with the US National Academy of Science and we follow the work of expert review groups like IARC, the WHO EMF project, ICNIRP and SCENIHR. All of these expert review organizations have vetting processes for their expert scientific review panels. In addition, our scientists have been following the RF science at national and international meetings as well as via Pubmed since at least the early 1990s.

Thank you for the link. FDA has no plan to nominate this issue for systematic review at the NTP Office of Health Assessment and Translation at this time.

My Follow Up Question 30: Why not? . Please I would think a systematic review is in order considering the exposure to babies and children for a lifetime.

FDA Answer to Follow-up Question 30: There is no need for NTP to do this work for the FDA. This can be done by the FDA if necessary. Also, there are already many systematic reviews available.

Additional Questions:

My Follow Up Question 31.

Children are handed wireless laptops in classrooms across the USA. Please explain why the FDA is not informing the parents that many laptops have minimum separation distance of 20cm or 8 inches that the device should be from the body to ensure FCC compliance. The FDA should be informing the public about this distance. Why aren't they.

See this http://news.arubanetworks.com/press-release/prince-georges-county-public-schools-creates-one-nations-largest-k-12-wi-fi-deployment

FDA Answer to Follow-up Question 31: The antenna in laptop computers is usually located along the top edge of monitor of the laptop. Opening the laptop to use it puts the antenna approximately 8-10 inches away from the viewer. Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 32.

What proof of safety is there that pregnant women are protected when it comes to this radiation. They are placing laptops on their bellies. Has the FDA looked at research on impacts on pregnancy? If so, please share what studies have been reviewed.
FDA Answer to Follow-Up Question 32: The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) section 3.6.4.1 Reproductive Effects is also a good place to start a review.
My Follow Up Question 33.
Send me documentation that children adequately covered by the current US guidelines. Children absorb the radiation deeper into their brain and body. Please explain why the FDA states "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."
Why does the FDA clarify that long term effects are still being researched and children are more vulnerable to this radiation? They will have more impacts as they will have a lifetime of exposure. Why doesn't the FDA state this clearly for parents?

FDA Answer to Follow-Up Question 33: Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women. The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) is also a good place to get a compilation of published reports.

My Follow Up Question 34.
The FDA has outdated information (highlighting Interphone 2010 results) on a webpage under the cellphones section entitled Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors."
https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm212273.htm
FDA Senior staff have been asked to update these webpages 4 times over the last two years and have not done so. Please explain why this outdated material is being left on the FDA website.

FDA Answer to Follow-up Question 34: Thank you for your review of the FDA website on this topic. Your concern regarding the information is noted. The information is still useful.

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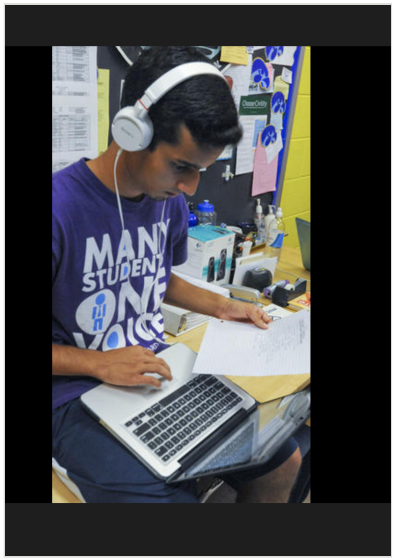
3Attached Images



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Microwave Emissions From Cell Phones Exceed Safety Limits in Europe and the US When Touching the Body

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ABSTRACT In our publications, we have shown both from measurements and computer modeling that the specific absorption rate (SAR) reduces by 10%–15% for every millimeter separation of the cell phone on account of rapidly diminishing EM fields in the near-field region of the cell phone antenna. This rapid reduction of SAR depending on the antenna and its location on the handset has been shown, both computationally and experimentally, regardless of the phantom model such as a flat phantom suggested for SAR compliance testing of devices in contact with the body, for a sphere phantom, and for head-shaped models used for SAR compliance testing of cell phones. Unfortunately, our observations in the past were based on SARs of only three cell phones. Expecting that the SARs for cell phones may exceed the safety limits for body contact, cell phone manufacturers have started to recommend that the devices can be used at 5–25 mm from the body even though it is difficult to see how to maintain this distance correctly under mobile conditions. The National Agency ANFR of France recently released the cell phone SAR test data for 450 cell phones that measure 10-g SARs reducing by 10%–30% for each millimeter distal placement from the planar body phantom. Their data corroborate our findings that most cell phones will exceed the safety guidelines when held against the body by factors of 1.6–3.7 times for the European/ICNIRP standard or by factors as high as 11 if 1-g SAR values were to be measured as required by the U.S. FCC.

INDEX TERMS XXXXX.

I. INTRODUCTION

Safety guidelines for radiofrequency (RF) microwave radiation have been proposed by the expert committees in the United States (Institute of Electrical and Electronics Engineers, IEEE) and by the International Committee for non-ionizing radiation protection (ICNIRP) of World Health Organization (WHO) [1], [2] as well as expert committees in Canada, Japan, Australia, etc. While the guidelines suggested by IEEE are followed by the U.S. Federal Communications Commission [FCC] in Washington, DC, the ICNIRP Standard is followed in Europe and many other countries in the world.

The IEEE safety guidelines followed by the FCC prescribe that the microwave emissions of a personal wireless device be limited to ensure that the mass-normalized power absorbed in any part of the body except limbs (specific absorption rate or SAR) does not exceed 1.6 W/kg for any 1 g of tissue in the shape of a cube [3]. The ICNIRP guideline is more lax and prescribes that the microwave radiation for such wireless devices not create an SAR in any part of the body of more than 2.0 W/kg for any 10 g of tissue. In published literature it has been reported that because of a larger volume for 10 g of tissue the ICNIRP standard will permit radiated powers of cell phones to be 2.5 to 3 times higher than those allowed by the IEEE/FCC standard [4]. The regulatory agency FCC requires that the personal wireless devices marketed in the U.S. meet the IEEE C95.1-1992 standard, thereby requiring lower radiated powers so as not to exceed SAR of 1.6 W/kg in any 1 g of tissue in the shape of a cube for all parts of the body except the limbs (''extremities'' such as hands, pinna, or the legs).

The associate editor coordinating the review of this manuscript and approving it for publication was Luyu Zhao.

II. RECENTLY SUGGESTED CHANGES BY INDUSTRY

Whereas the cell phones are often used held against the ear canal or against the body in shirt or pant pockets and are therefore very close to the body, the cell phone manufacturers

TABLE 1. SARs in W/kg measured for some representative telephones held against the flat phantom model of the body at manufacturer-suggested distances D and at distances of 5 and 0 mm as for actual use by consumers (taken from ANFR Test Report [10]).

Make	MODEL	SAR at Mfr. Suggested Distance D	SAR (5mm)	SAR (0mm)	Percent increase in SAR for	
					From D to 0mm	From 5 to 0mm
POLAROID	PRO 881A	1.05 (15 mm)	3.63	7.42	13.90%	15.40%
HTC	ONE SV	0.366 (15 mm)	2.256	7.183	22.00%	26.10%
BLACKBERRY	Z 10	0.934 (15 mm)	3.18	6.8	14.20%	16.40%
MOTOROLA	MOTOLUXE	0.254 (25 mm)	2.96	5.86	13.40%	14.60%
ORANGE	NEVA 80 (ZTE BLADE V770)	1.39 (15 mm)	3.62	5.79	10.00%	9.90%
HUAWEI	P9 (EVA-L09)	1.32 (15 mm)	3.18	5.6	10.10%	12.00%
MOTOROLA	RAZR I	0.507 (25mm)	2.27	5.51	10.00%	19.30%
SONY	XPERIA S CITIZY LT26i	0.748 (15 mm)	2.253	5.45	14.20%	19.30%
APPLE	iPHONE 5	0.825 (10 mm)	1.453	5.321	20.50%	29.60%
SAMSUNG	GALAXY S 5 SM-G900 F	0.545 (15 mm)	1.55	3.55	13.30%	18.00%
ECHO	NOTE	1.35 (5 mm)	1.35	4.15	25.20%	25.20%
APPLE	iPHONE 5C	1.11 (5 mm)	1.11	3.11	22.90%	22.95%
SAMSUNG	GALAXY J7 (SM-J710FN)	1.29 (5 mm)	1.29	3.56	22.50%	22.50%

in the last 5-10 years have started to recommend that they be held 5, 10, or 15 up to 25 millimeters from the body. We assume this additional spacing between the cell phone and the body was recommended because of our past publications that these wireless devices will not pass the safety standards when held against the body on account of the very rapidly diminishing EM fields close to radiating antennas [4]–[7], [10]. In spite of the manufacturer recommendations, we find it hard to believe that one can carry out a conversation when the telephone is held up to 25 millimeters away from the ear canal particularly in crowded noisy environments or that these recommended distances can be maintained consistently under mobile conditions without use of a spacer to maintain the suggested distances of 5 to 25 millimeters.

III. RECENT ANFR (FRANCE) CELL PHONE TEST MEASUREMENTS

On June 1, 2017, the National Agency (ANFR) of France released the cell phone SAR test results on hundreds of cell phones that they had been testing at accredited laboratories since January 2012 [9] using a two-sided version of the IEEE-recommended SAM model or a flat body-simulant model. The ANFR tests differed from regulatory tests in that they measured SARs with separation distances D recommended by individual manufacturers as well as placements that were closer at 5 and 0 millimeter to mimic actual use conditions by consumers holding the wireless device against the body, e.g. in their pockets where SARs higher than the safety limits have also been previously reported by us in peer reviewed published literature [10].

The ANFR test program measured the 10 g SAR called for in the European/ICNIRP standard at three positions of use: the manufacturer-suggested distance D (5, 10, 15, or 25mm) and 5 and 0 mm as for most likely use close to the body (5 mm presumably because of thickness of clothing). A strength of the ANFR results is they have tested 450 cell phones as against our very limited data based on 3 telephones [6], [10]. As the ANFR had tested a large number of cell phones resulting in a very large report [9], we decided to select a limited number of 13 telephones for this paper to illustrate the results. The SARs measured for these 13 selected cell phones are given in Table 1. Shown in this Table is that the telephones give SARs that are within ICNIRP guideline of 2.0 W/kg for manufacturer-suggested distances D (5, 10, 15, or 25 mm), but give SARs that are considerably higher than those of ICNIRP guidelines (by factors of 1.6 to 3.7 times) when the telephones are held against the body to mimic likely actual use conditions. In this context it should be mentioned that the SARs would be even higher by an additional multiplier of 2.5 to 3 or a factor of up to 11 times higher if 1 g values required by the IEEE/FCC standard were measured. All of the 13 selected ANFR-tested devices of Table 1 will not pass the US/FCC safety compliance requirement of 1.6 W/kg for any 1 g of tissue [3]. In the last column of Table 1 we give the calculated increase of SAR per millimeter of reduced spacing for each of the wireless devices from manufacturer-recommended distance D to zero and from 5 mm to zero, respectively. The increase in SAR for each millimeter of proximal placement of the wireless device varies from 10 to 30% which is higher than our previously reported results of 10-15% based on a very limited number—only three cell phones. However the ANFR results do reinforce our additional previously published observations [5] that Standard Anthropomorphic Mannequin (SAM) with tapered plastic

spacer that creates an artificial separation of the wireless device by 6-10 mm will reduce the measured SAR and cannot be trusted as a method for SAR compliance testing. Another thing to observe from the data in columns 4 and 5 is that the SAR is higher by a factor of 2 to 3 for a 5-millimeter closer placement of the wireless device. In [6] we have also proposed this as the reason for a higher SAR for children and for women and men with thinner pinna and skulls resulting in radiating wireless devices being placed closer to the brain in stronger radiated EM fields.

IV. INTERPRETATION OF THE ANFR TEST RESULTS OF TABLE 1

All 13 of the selected telephones of Table 1 fail the SAR requirements mandated by the ICNIRP/European Standard and the US FCC Standard because of the following considerations:

1) The ICNIRP guidelines state that the 10-g SAR for conditions of actual use be no more than 2 W/kg and FCC requires compliance with IEEE Standard C95.1-1991 [1] which is set in terms of 1 g SAR of 1.6 W/kg. It has been shown in peer-reviewed published literature [4], [6] that because of the fairly shallow penetration of RF energy coupled to the tissues, the 1 g SAR is typically 2.5-3 times the 10-g SAR.
2) For cell phones held against the pinna, the measured 1 or 10 g SAR will also be much higher if SAM had not used the lossless artificial plastic spacer in lieu of the tissue-simulant human pinna. As pointed out in [5] and [6], the tapered plastic spacer artificially separates the radiating cell phone antenna by up by up to 10 mm additional spacing for the RF coupled regions of the head resulting in underestimation the 1 g and 10 g SAR by a factor to 2-4. This factor of 2-4 higher SAR is also borne out by the ANFR the ANFR measured results in Table 1 where higher values of SAR are reported in columns 3 and 4 that are for separation distances of 15 and 5 mm respectively.

V. CONCLUSIONS

It is important that safety compliance testing be done under realistic conditions of actual use of the cell phones by the present day users. This should include telephones held close to the body at 0 millimeter spacing and against the tissue-simulant pinna rather than a pinna simulated by a tapered plastic spacer. For the latter, phantom models of the actual users such as children and women and men of smaller head sizes should be used rather than the large head size of Army Recruits used for SAM. The children and women are known to have thinner pinna and skulls which results in closer placements by several millimeters of the radiating antennas to the brain. It is not sufficient for manufacturers to start recommending that the microwave radiating devices be held at distances of 5 to 25 millimeters away from the body to reduce measured SAR to meet the safety standards since these suggested distances cannot be maintained correctly without use of properly attached spacers. Even though ANFR of France has to date released the higher SAR data that does not meet the safety compliance standards when the telephones are held against the body, similar results have also been obtained by independent testing in Canada [11].

Because of the increasing popularity of wireless phones all over the world with use by over 90-95% of populations, it is important that the regulatory agencies in various countries define correct conditions for SAR testing that will cover a majority of users including children.

ACKNOWLEDGMENT

The author would like to thank the contributions of Dr. Marc Arazi of Paris, France, in providing the English translation of the fairly large ANFR TEST Report [9] and Ms. Theodora Scarato in carefully preparing a shortened version of the large ANFR report with data on 450 tested devices into columns 1-5 of Table 1 for 13 selected telephones for illustrative purpose.

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Authors' photographs and biographies not available at the time of publication.

The Honorable Alex Azar
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Sent electronically to ombuds@oc.fda.gov, DICE@fda.hhs.gov, jeff.shuren@fda.hhs.gov, Stephen.Hahn@fda.hhs.gov, Secretary@HHS.gov,

Re: FDA Literature Review on Cell Phones

Dear Honorable Commissioner Hahn, Honorable Secretary of Health and Human Services Alex Azar and
Dr. Shuren Director of the FDA Center for Devices and Radiological Health;

The selective FDA review is not in line with the majority of the scientific community on the issue of RF EMF health effects. I and more than 220 scientists from 41 countries, many of them EMF-active, have signed the International EMF Scientist Appeal (EMFscientist.org, 2015), which calls on the World Health Organization (WHO), the United Nations, and all member nations to issue health warnings about the risks of RF and ELF EMF exposure and to adopt much stronger exposure guidelines to protect humans than the outdated International Commission on Non-Ionizing Radiation Protection (ICNIRP) suggest. Please be aware that ICNIRP standards, while slightly different from the FCC standards, are also based on avoiding thermal RF effects for short periods of time -- acute (not chronic) exposures. In this regard, ICNIRP guidance ignores thousands of studies showing non-thermal RF effects.

Multiple studies (not referred to in the selectiveFDA review) have appeared since the classification of RF as possible human carcinogen, Group 2B, by the International Agency for

Research on Cancer (IARC) in 2011 (IARC, 2013). These studies from our laboratory and many others demonstrate carcinogenic potential of non-thermal RF exposures and preferential primary mechanism through induction of reactive oxygen species (ROS), see for review (Belpomme, Hardell, Belyaev, Burgio, & Carpenter, 2018; Belyaev, 2015a, 2015b, 2017, 2019; Belyaev et al., 2016).

The National Toxicology Program (NTP) findings along with recent replicated animal studies from Germany (Lerchl et al., 2015), supplemented other animal studies and provided sufficient evidence for carcinogenicity of cellphone exposure in animals. The NTP results on schwannoma and glioma are of special concern since they corroborate human epidemiology findings on human use of cell phones where similar tumors were found. Studies with chronic exposures have also provided evidence for possible mechanisms of RF non-thermal effects, which involve production of reactive oxygen/nitrogen species. According to the unanimous opinion of the 19-member peer review panel that examined NTP study (NTP, 2018), its results provide "clear evidence"—the highest standard of proof—that RF fields cause schwannomas (malignant tumors of the Schwann cells that sheath all myelinated nerves) in the hearts of male rats.

Taking into account the evidence from human epidemiological studies, I concur with a number of experts in the field that evidence at this time supports the classification of RF exposure from cell phones as human carcinogen according to the generally accepted Bradford Hill criteria (Carlberg & Hardell, 2017; Miller et al., 2018). The NTP study also reported less clear evidence that RF causes various other tumors (gliomas in the brain, pheochromocytomas in the adrenal gland, and tumors of the prostate and pancreas) (NTP, 2018). In contrast to the selective FDA review, the IARC advisory group of 29 scientists from 18 countries has recently stated that the new bioassay and mechanistic evidence warrants high-priority re-evaluating the RF-induced carcinogenesis (Marques et al., 2019).

Based on these considerations, I urge the FDA to withdraw their selective report from publication, convene an independent expert group to evaluate all the evidence including mechanistical and in vitro studies, which were omitted by the FDA report, and take steps to advise the public on how to reduce exposures to radiation at this time.

Igor Belyaev, PhD, Dr.Sc.
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The Honorable Alex Azar
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Re: Call for Retraction of Flawed FDA Literature Review on Cell Phones

Dear Honorable Commissioner Hahn, Honorable Secretary of Health and Human Services Alex Azar and Dr. Shuren, Director of the FDA Center for Devices and Radiological Health;

As experts in the field of bioelectromagnetics, we are writing to urge you to retract a recent flawed report entitled "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer. Further, we ask you to remove and replace recent revisions to FDA websites that invoke this recent report as grounds for asserting that cellphone radiation has no known health effects, contrary to official reviews in other high-technology nations.

As many of us have detailed in letters sent to your offices, this report does not merit publication or posting on FDA's website as it represents a highly limited review of the literature, contains "numerous scientific errors" omitting important studies for review and including studies that have been rejected for their flawed methods, and fails to acknowledge official actions by governments in France, South Korea, Belgium, Cyprus, European Parliament and recommendations by the American Academy of Pediatrics and California Department of Public Health that have issued specific advice about why and how to reduce exposures to cellphones and other wireless radiation sources. By dismissing scientific evidence of adverse effects and downplaying the need for individuals to take precautionary measures when using cell phones, the FDA review does not comport with the Agency's mission of protecting and promoting public health.

Contrary to what the report and FDA website assert, there is no "scientific consensus" that cell phone radiation and 5G are safe as evidenced by the official statements of hundreds of scientists and medical organizations.

The FDA in collaboration with US health and environmental agencies should convene an interdisciplinary panel of independent experts to provide a systematic review of relevant literature on cell phones and wireless radiation and health to guide the agency in its policy recommendations. Further, any such review should also consider the growing evidence of environmental effects along with public health impacts of exposures as well as relevant policy developments.

Signed,

Ronald Melnick PhD, former National Institutes of Health Scientist
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February 27, 2020

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Center for Devices and Radiological Health
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RE: FDA Literature Review on Radiofrequency Radiation and Cancer

Dear Dr. Shuren,

I am writing this letter to detail major incorrect statements and omissions of relevant data in the FDA document titled "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer." I led the design of the National Toxicology Program's (NTP) toxicity and carcinogenicity studies on cell phone radiation and I strongly believe that the anonymously written FDA document misrepresents the utility of the NTP study for assessing human health risks. In addition, the report's casual dismissal of both the mechanistic findings and the numerous results from epidemiological studies that have shown increased cancer risks associated with exposure to radiofrequency radiation (RFR) are inconsistent with the FDA's stated core mission "to protect and promote the public health."

Regarding the NTP studies on cell phone RFR, an expert peer-review panel discussed the results for 3 days and concluded (NTP TR-595; Peer-Review Report 2018) that this carefully designed and conducted study provided "clear evidence of carcinogenic activity." In contrast to the NTP and peer-review conclusions, the FDA claims that whole-body exposures used in the NTP study cannot be related to the local RFR exposures a human receives while using a cell phone. The dismissal of the NTP study results by the FDA is rather peculiar since it was the FDA's Center for Device and Radiological Health that requested the toxicity and carcinogenicity of RFR in experimental animals (CDRH nomination of RFR) "to provide the basis to assess the risk to human health," and FDA scientists were fully aware of the exposure methodology that was used in the NTP study long before those studies were begun.

The NTP study was designed to provide accurate organ-specific dosimetry that could be used to quantify risks for any adverse effect that might be identified. Most people who check on the RF emissions from their cell phones learn that the Federal Communication Commission (FCC) requires that local tissue exposures be lower than 1.6 W/kg averaged over any one gram of tissue. In the NTP study, the exposures to the brain of rats were approximately 1.5, 3.0, and 6.0 W/kg – close to the FCC's local exposure limit. For experimental studies in small groups of laboratory animals, these values are unusually close to allowable local tissue exposures in humans and require minimal extrapolation to estimate human cancer risk.

The FDA report complains that the whole-body exposures in the NTP study at 6 W/kg was 75 times higher than the exposure limit for the general population (the lower doses were 38- and 19-times that limit for the general population, but only 8- and 4-times the exposure limit for workers). However, whole body exposures provide little information on organ-specific exposure levels. When an individual holds a cell phone next to their head, the important exposure for consideration of health risk is the local exposure. That is why the NTP study design focused on the local exposure intensities. If the animal studies had used the whole-body exposure limit of 0.08 W/kg, then the exposure to the brain of

exposed animals would have been 20-fold less than the FCC's local exposure limit for the general public, i.e., a useless study for assessing human risk. It is misleading for the FDA document to ignore the local exposure limit of 1.6 W/kg and its importance for assessing organ-specific cancer risk.

The FDA document criticizes studies that did not perform histopathology evaluations blinded to the dose group, including the NTP study. However, as was pointed out previously[1], the final diagnosis of lesions in the NTP study was done by a group of pathologists who did not know whether the slides they were examining came from an exposed or an unexposed animal. In addition, for anyone questioning the diagnosis of any tissue in this study, all of the slides from the NTP studies are available for examination at the NTP archives.

The FDA document also suggests without evidence that the carcinogenic effects in rats exposed to 6 W/kg were due to the loss of their ability to maintain their body temperatures during the exposures. However, measured body temperatures were within 1 ^{o}C of their normal body temperature, there were no differences in body weights between exposed and sham control rats in the 2-year study, there was no indication of tissue damage in the 28-day study, and there were no exposure-related clinical observations in the 2-year study (NTP TR-595). Thus, it is clear that animals tolerated the exposure levels used in the NTP study. The peer reviewers of the NTP studies were fully aware of all issues raised in the FDA document, yet still concluded that the results of those studies showed clear evidence of carcinogenic activity. FDA scientists had opportunity to offer criticisms of the NTP study prior to and during the 3-day peer-review, but did not. Did the FDA somehow have an epiphany regarding the human relevance of the NTP cancer data or was there some other factor influencing their decision to dismiss those results?

Lastly, the FDA document misstates the results of the genetic toxicology tests in animals from the NTP study. For example, the FDA document claims there were "no statistically significant increases in DNA damage in female rats or either mouse sex" and the increases in DNA damage in male rats "was not statistically significant," when in fact there were significant increases and significant trends in DNA damage in the frontal cortex of male mice exposed to GSM or CDMA modulated RFR and in the frontal cortex and hippocampus of male rats exposed to CDMA (NTP TR-595).

The FDA document also claims there is a "lack of biological mechanistic plausibility," while eight *in vivo* studies cited in that document provided evidence of increased oxidative stress associated with exposure to RFR and 15 studies provided evidence of genotoxicity. In addition, many relevant *in vivo* studies showing evidence of oxidative stress were not reported in the FDA document and there are many *in vitro* studies that have found oxidative stress associated with exposure to RFR[2]. A true risk analysis should consider both *in vivo* and *in vitro* studies when ascertaining biological mechanistic plausibility. A characteristic of many human carcinogens is the induction of oxidative stress that can subsequently lead to mutations, chromosomal translocations, and genetic instability.[3] Thus, there does exist a biologically plausible mechanism for the induction or progression of tumors associated with

1 Melnick RL (2019). Commentary on the utility of the National Toxicology Program study on cell phone radiofrequency radiation data for assessing human health risks despite unfounded criticisms aimed at minimizing the findings of adverse health effects. *Environ Res*. 168:1-6.

2 Yakymenko I, Tsybulin O, Sidorik E, et al. (2016). Oxidative mechanisms of biological activity of low-intensity radiofrequency radiation. *Electromagn Biol* Med 35: 186-202.

3 Smith MT, Guyton KZ, Gibbons CF, et al. (2016). Key characteristics of carcinogens as a basis for organizing data on mechanisms of carcinogenesis. *Environ Health Perspect*. 124:713-721.

exposure to RFR. For studies that did not show evidence of carcinogenicity or genotoxicity, the FDA document did not comment on whether or not those studies were adequately designed with respect to animal group size, exposure levels and duration of exposure.

Regarding human studies, the FDA document cites the study by Little (2012) in which it was reported that glioma trends in the US between 1997 and 2008 have remained relatively constant, but omitted the study by Philips et al. (2018)[4] that reported a doubling in incidence of glioblastoma (frontal and temporal lobes) in England between 1995 and 2015. The latter study was published in June 2018, which is within the timeframe (August 2018) for epidemiological studies included in the FDA document.

The FDA document identified several human studies that reported risks of glioma, acoustic neuroma, and other tumor types that were increased among cell phone users. In each case, the document focused on limitations in those studies to raise doubt about their reliability for assessing cancer risk. Two limitations specified for most case-control studies included selection and recall bias. However, the FDA document neglected to discuss the impact of the study by Momoli et al.(2017),[5] which re-analyzed the Canadian data that was included in the Interphone study and showed that there was no effect on the risk of glioma after adjustments were made for selection and recall biases; the odds ratios (OR) for glioma were significantly increased when comparing the highest quartile of use to those who were not regular users whether or not adjustments were made: OR = 2.0, 95% confidence interval 1.2–2.4 without adjustment; OR = 2.2 95% confidence interval 1.3–4.1 with adjustments. Evidently, selection and recall biases do not explain the elevated brain cancer risks associated with use of cell phones in that study.

Thus, while there are reliable animal studies, mechanistic studies, and animal studies showing increased cancer risks associated with exposure to cell phone RFR, the FDA document dismisses nearly the entirety of those studies to enable the agency to conclude that there is insufficient evidence to support a causal association between RFR exposure and tumorigenesis. According to the FDA, animal studies are not useful for studying potential effects in humans (though animal studies are used in drug development) and the human studies "were subject to flaws and inaccuracies." Yet, every known human carcinogen is carcinogenic in animals when adequately tested. Public health agencies including the NTP, US EPA, IARC, and the FDA have a long tradition of relying on the relevance of rodent toxicology/carcinogenicity studies to identify hazardous agents and assess human health risks in order to implement public health protective policies. The statement in the FDA report that "if any risk does exist, it is extremely low" is very misleading since the FDA has not performed a quantitative risk assessment on any of the available data sets and, because of the widespread use of cell phones in the US and world-wide, even a small increase in cancer risk would have a serious public health impact.

Based on the FDA review, which is not a risk analysis as stated in the document, the message for the general public appears to be that precautionary measures for use of cell phones are not necessary in spite of the fact that numerous studies have provided compelling evidence of increased cancer risk

4 Philips A, Henshaw DL, Lamburn G, O'Carroll MJ. (2018). Brain tumours: rise in glioblastoma multiforme incidence in England 1995-2015 suggests an adverse environmental or lifestyle factor. *J Environ Public Health*. Article ID 7910754,

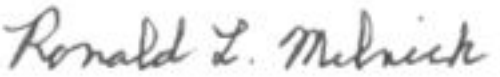
5 Momoli F, Siemiatycki J, McBride ML, et al. (2017). Probabilistic multiple-bias modeling applied to the Canadian data from the Interphone study of mobile phone use and risk of glioma, meningioma, acoustic neuroma, and parotid gland tumors. *Am J Epidemol*. 186:885-893.

associated with exposure to cell phone RFR. This is an irresponsible message for a government agency that claims its mission is to protect consumers and promote the public health.

The statement on the FDA website (https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard) that there is a "scientific consensus on cell phone safety" is totally wrong and should be removed since there is no scientific consensus supporting this claim. In contrast, numerous experts in the field have reported evidence that current levels of cell phone radiation can be harmful to human health.

In conclusion, the FDA document has serious flaws and inaccuracies, as well as omissions of relevant data. Hence, in consideration of public health, it is important that FDA immediately retract their review on radiofrequency radiation and cancer.

Sincerely,



Ronald L. Melnick, Ph.D.
Retired toxicologist NTP, NIEHS

Press Statement from Dr. Albert Manville on the FDA Report

In a February 13, 2020, news release from MedPage Today, an anonymous, nonscientific review asserts that, according to the FDA, cellphones have …"no quantifiable adverse health effects in humans," but FDA suggests that further research should be conducted in vulnerable individuals who may be more predisposed to tumors from "short but intense RF exposure" above current limits.

As a certified wildlife biologist and Ph.D. environmental scientist who has studied the impacts of radiation on migratory birds, other wildlife, and humans since the late 1990s, the statement credited to the FDA is preposterous, without any scientific credibility, and at a minimum deserves a retraction by the FDA.

There currently are well over 500 scientific, peer-reviewed papers addressing impacts of non-ionizing, non-thermal radiation on laboratory animals — many of the studies directly applicable to human health and safety. I'm coauthoring a detailed scientific paper on these impacts. When I worked as a wildlife biologist for the U.S. Fish & Wildlife Service for 17 years, I collaborated with the late Dr. Ted Litovitz in 2000. Dr. Litovitz and his colleagues studied the impacts of low-level, non-thermal radiation from the standard 915 MHz cell phone frequency on chicken embryos. In their laboratory studies, control/non-treated embryos suffered no effects, but some of the treated/irradiated embryos died — at levels as low as 1/10,000 the normal level of cell phone radiation exposure to humans. This was an eye-opener! The findings were published by DiCarlo and others in 2002 in the Journal of Cellular Biochemistry. Meanwhile, I worked closely with collegues from Europe, including Balmori, Hallberg, Everaert, and Bauwens on the impacts of cell towers on wild migratory European birds. The results of their field research were equally astounding. Where healthy, breeding bird populations had persisted, once cell towers were installed and operating, nest and site abandonment, plumage deterioration, locomotion problems, reduced survivorship, and death were noted in House Sparrows, White Storks, Rock Doves, Magpies, Collared Doves, and other species. This was documentation in the field of some very troubling consequences of the impacts of cell tower radiation on wildlife.

With these scientific findings, I was instrumental in getting the Department of Interior to convince the First Responder Network Authority, National Telecommunications and Information Administration, Department of Commerce, to begin the process of an Environmental Impact Statement under the National Environmental Policy Act in early 2014. This was the first time one federal department had convinced another department to conduct such a review. While the NEPA review was ultimately scuttled, the results of previous studies clearly showed that radiation has impacts on wildlife, and therefore needed extensive further scientific and public review. The consequences to human health and safety were implicit.

The FDA needs to carefully review the existing and growing scientific record. The current FDA statement is irresponsible, unfounded, and sets a dangerous precedent — especially in this age of "fake news" and "alternative facts." It needs to be corrected or retracted.

Respectfully submitted.

Albert M. Manville, II, Ph.D.; Certified Wildlife Biologist (CWB), The Wildlife Society; Senior Lecturer and Adjunct Professor, Krieger School of Arts and Sciences, Advanced Academic Programs, Johns Hopkins University, Wash DC Campus; and retired Senior Wildlife Biologist, Division of Migratory Bird Management, U.S. Fish & Wildlife Service, Wash. DC HQ Office (17 years);

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Coláiste na hOllscoile Corcaigh

29/02/2020

Tom Butler PhD MSc |**Professor**

To: Jeffery Shuren, Director of the Center for Devices and Radiological Health, FDA.

Re: Response to FDA Center for Devices and Radiological Health (CDRH) Report: *Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer*

Dear Jeffery,

I wish to voice my concerns about the validity, reliability, and integrity of the report titled: *Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer*.

To begin, I note that the mission of the FDA's Center for Devices and Radiological Health (CDRH) is as follows:

> *… the Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.*

It is clear that the Center's central mission is to assess medical devices and radiation-emitting products in the field of medicine. Given the ongoing digital transformation of the healthcare industry focusing on the widespread use of wireless devices across hospitals and healthcare facilities, including the Internet of Things, enabled by 5G, there is an onus on the FDA to ensure the general safety of wireless technologies to patients and those with chronic illnesses and disabilities in the face of mounting scientific evidence of the risks posed by wireless technologies of all types.

The FDA seems unaware of, or is it simply ignoring, the overwhelming body of scientific evidence on non-thermal effects, and not just the carcinogenicity, of non-ionizing ionizing radiofrequency radiation (RFR). Take, for example, a recent research review by independent researchers on the health risks of microwave RFR concludes that "*the literature shows there is much valid reason for concern about potential adverse health effects from both 4G and 5G technology"* and that extant research *"should be*

viewed as extremely conservative, substantially underestimating the adverse impacts of this new technology."[1]

The above review by US scientists reported that peer-reviewed studies find the following adverse health effects well below the safety limits set by the FCC and ICNIRP guidelines:

- *"carcinogenicity (brain tumors/glioma, breast cancer, acoustic neuromas, leukemia, parotid gland tumors),*
- *genotoxicity (DNA damage, DNA repair inhibition, chromatin structure), mutagenicity, teratogenicity,*
- *neurodegenerative diseases (Alzheimer's Disease, Amyotrophic Lateral Sclerosis),*
- *neurobehavioral problems, autism, reproductive problems, pregnancy outcomes, excessive reactive oxygen species/oxidative stress, inflammation, apoptosis, blood-brain barrier disruption, pineal gland/melatonin production, sleep disturbance, headache, irritability, fatigue, concentration difficulties, depression, dizziness, tinnitus, burning and flushed skin, digestive disturbance, tremor, cardiac irregularities,*
- *adverse impacts on the neural, circulatory, immune, endocrine, and skeletal systems."*

The above findings were independently verified by the research team using 5,400 studies in the MedLine database.

Given the foregoing, a question begs as to *whether the FDA had the required competencies to perform its recently published review?* Justification for this question arises from the thousands of relevant studies on the MedLine database identified by independent researchers, as opposed to the 282 studies referenced by the FDA, and the *"approximately 70 relevant epidemiological studies"* mentioned in the Executive Summary and which informed the FDA's conclusions. The remaining peer-reviewed studies considered by the FDA appear to have been excluded on highly questionable grounds. All this gives the lie to the claim that *"[t]he Agency has taken a comprehensive approach to evaluating the available scientific evidence regarding the impact of radiofrequency radiation (RFR) exposure on human health."* Furthermore, however limited the Center's internal competencies may be, the FDA's network of experts[2] are focused on medical practice and the use of various devices employed by health care professionals, and are not subject matter experts in 2-4G, Wifi and 5G telecommunications systems and devices. This is important, as 4G, Wifi and 5G technologies are now being employed across the healthcare industry and in general use across the population. The risks posed by such technologies deserve cross-agency attention and review by independent, competent experts across multiple disciplines, without a single conflict of interest.

Following on from the points made above, I accept that the FDA may call on physicians/scientists with relevant expertise to conduct its scientific reviews, however, the report is silent on which scientists, physicians or engineers conducted the review, the levels of expertise they possessed, and any conflicts of interest they had. This places the second question mark over the trustworthiness of the report—there are, however, several other critical questions that require to be answered in full.

Why were ceratin epidemiological studies excluded from the review?

The FDA report is significantly incomplete and therefore inaccurate, given the acknowledged timeframe and intention to include *"more recent, relevant peer-reviewed publications through August 2019."* A simple example suffices to demonstrate this. The findings of 13 important epidemiological studies are presented below. Also below is a reference to a report that refutes the claims made by the Swedish Radiation Safety Authority cited in the FDA report. The 13 studies were ignored and omitted

[1] Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. Toxicology Letters.
[22] https://www.fda.gov/media/120990/download

by those conducting the review. *Why did this omission take place?* The inclusion of the findings of this recent body of research would have made the report's conclusions untenable. A short review of the 13 studies will support my contention.

First, if the FDA team were using MedLine as indicated, they surely would have identified a study in The Lancet Neurology. The findings of this study places the FDA conclusions in serious doubt viz. *"CNS cancer is responsible for substantial morbidity and mortality worldwide, and the incidence increased between 1990 and 2016. Significant geographical and regional variation in the incidence of CNS cancer might be reflective of differences in diagnoses and reporting practices or unknown environmental and genetic risk factors. Future efforts are needed to analyze CNS cancer burden by subtype."*[3] Below is an excerpt from the findings of another relevant study which the FDA ignored.[4]

Table 1 The global death and incidence of all cancers and 29 specified cancer groups in 1990 and 2017

Tumor types	1990				2017			
	Death		Incidence		Death		Incidence	
	Number 10^3(95% UI)	Age-standardized per 100,000 (95% UI)	Number 10^3(95% UI)	Age-standardized per 100,000 (95% UI)	Number 10^3(95% UI)	Age-standardized per 100,000 (95% UI)	Number 10^3(95% UI)	Age-standardized per 100,000 (95% UI)
Brain and nervous system cancer	142 (171–117)	3.04 (3.58–2.56)	194 (234–159)	3.97 (4.71–3.33)	247 (265–213)	3.12 (3.34–2.68)	405 (443–351)	5.17 (5.64–4.46)
Thyroid cancer	22 (24–21)	0.55 (0.6–0.52)	95 (101–90)	2.11 (2.24–2.01)	41 (44–40)	0.52 (0.56–0.51)	255 (272–246)	3.15 (3.36–3.03)

While these studies did not link the significant increase in brain and CNS cancer to cellphone and RFR exposure, a recent study by US economists does.[5] That study demonstrates *"that mobile phone subscription rates are positively and statistically significantly associated with death rates from brain cancer 15-20 years later. As a falsification test, we find few positive associations between mobile phone subscription rates and deaths from rectal, pancreatic, stomach, breast or lung cancer or ischemic heart disease."* This 25-year cross country analysis provides solid evidence of the link between mobile phone use and cancer when positioned alongside epidemiological studies.

These trends are also evident in the findings of other studies. A research review of the incidence of glioblastoma multiforme tumours in England during 1995–2015 reported a *"a sustained and highly statistically significant ASR [(incidence rate)] rise in glioblastoma multiforme (GBM) across all ages. The ASR for GBM more than doubled from 2.4 to 5.0, with annual case numbers rising from 983 to 2531. Overall, this rise is mostly hidden in the overall data by a reduced incidence of lower-grade tumours."*[6] The study did not focus on RFR as the cause, so the findings must be considered 'open to interpretation' in this regard, as other environmental mechanisms cannot be ruled out. However, the following figures are clear and unambiguous. In the UK in 1995, 553 frontal lobe tumours were diagnosed in patients, while 1231 were found in 2015. Likewise, 334 temporal lobe tumours were reported in 1995, while 994 were diagnosed in 2015. The increase in these cancers of the CNS are clear and unambiguous. The authors of this study argue that:

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[3] Patel, A. P., Fisher, J. L., Nichols, E., Abd-Allah, F., Abdela, J., Abdelalim, A., ... & Allen, C. A. (2019). Global, regional, and national burden of brain and other CNS cancer, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. The Lancet Neurology, 18(4), 376-393.

[4] Lin, L., Yan, L., Liu, Y., Yuan, F., Li, H., & Ni, J. (2019). Incidence and death in 29 cancer groups in 2017 and trend analysis from 1990 to 2017 from the Global Burden of Disease Study. Journal of hematology & oncology, 12(1), 96.

[5] Mialon, H. M., & Nesson, E. T. (2019). The Association Between Mobile Phones and the Risk of Brain Cancer Mortality: A 25-year Cross-country Analysis. Contemporary Economic Policy. https://doi.org/10.1111/coep.12456.

[6] Philips, A.. Henshaw, D., L Lamburn, G. & M. O'Carroll, (2018). Brain tumours: rise in Glioblastoma Multiforme incidence in England 1995–2015 suggests an adverse environmental or lifestyle factor, Journal of Environmental and Public Health, vol. 2018, Article ID 7910754.

"The rise cannot be fully accounted for by promotion of lower–grade tumours, random chance or improvement in diagnostic techniques as it affects specific areas of the brain and only one type of brain tumour. Despite the large variation in case numbers by age, the percentage rise is similar across the age groups, which suggests widespread environmental or lifestyle factors may be responsible. This article reports incidence data trends and does not provide additional evidence for the role of any particular risk factor."

It is significant that the frontal and temporal lobes receive the greatest exposure to RFR from smartphones and wireless devices.

A comprehensive review of the incidence of primary brain and other central nervous system tumors diagnosed in the United States during the period 2009–2013, found quite small, but statistically significant increases in some categories of CNS tumours and none in others.[7] To be sure, in this study published in 2016, the increase in the incidence of tumours reported were not as alarming as those in the UK study. However, this is only the first in a series demonstrating an upward trend.

A related U.S. study echoed the previous findings, but found an *"an increasing medulloblastoma incidence in children aged 10–14 years."*[8] Another recent study on children found statistically-significant changes in several sub-types of CNS cancers, notably gliomas, in the period 1998-2013.[9] The latter study concluded that *"Continued surveillance of pediatric CNS tumors should remain a priority given their significant contribution to pediatric cancer deaths."*

In keeping with studies that provide compelling evidence for concern, a recent review study of epidemiological studies on brain and salivary gland tumours in relation to mobile phone use found the cumulative evidence to be inconclusive but indicated that such cancers may have a long latency (i.e. greater than 15 years) and clear evidence may emerge in the future. Nevertheless, scientists argue that childhood exposure to RFR devices is of significant concern.[10] There is also evidence that RFR from cell phones may be triggering breast cancer in young women who carry their devices on or near their breasts.[11] In addition, while the extensive studies by the Hardell Group cited in the FDA review demonstrate increases in cancers of the CNS in Sweden, these findings have been recently replicated in Denmark.[12]

In a general context, the U.S. Center for Disease Control and related research finds that non-Hodgkin lymphomas, central nervous system tumors (including brain cancers), renal, hepatic and thyroid

[7] Ostrom, Q. T., Gittleman, H., Xu, J., Kromer, C., Wolinsky, Y., Kruchko, C., & Barnholtz-Sloan, J. S. (2016). CBTRUS statistical report: primary brain and other central nervous system tumors diagnosed in the United States in 2009–2013. Neuro-oncology, 18(suppl_5), v1-v75.

[8] Khanna, V., Achey, R. L., Ostrom, Q. T., Block-Beach, H., Kruchko, C., Barnholtz-Sloan, J. S., & de Blank, P. M. (2017). Incidence and survival trends for medulloblastomas in the United States from 2001 to 2013. Journal of neuro-oncology, 135(3), 433-441.

[9] Withrow, D. R., de Gonzalez, A. B., Lam, C. J., Warren, K. E., & Shiels, M. S. (2018). Trends in pediatric central nervous system tumor incidence in the United States, 1998-2013. Cancer Epidemiology and Prevention Biomarkers, cebp-0784.

[10] Röösli, M., Lagorio, S., Schoemaker, M. J., Schüz, J., & Feychting, M. (2019). Brain and Salivary Gland Tumors and Mobile Phone Use: Evaluating the Evidence from Various Epidemiological Study Designs. Annual review of public health, 40.

[11] West, J. G., Kapoor, N. S., Liao, S. Y., Chen, J. W., Bailey, L., & Nagourney, R. A. (2013). Multifocal breast cancer in young women with prolonged contact between their breasts and their cellular phones. Case reports in medicine, 2013.

[12] Swedish Radiation Protection Foundation (2017). Brain tumors are increasing in Denmark https://www.stralskyddsstiftelsen.se/wp-content/uploads/2017/01/denmark_cnstumorsrising_2017-01-20.pdf

tumours have increased recently among adolescent Americans.[13, 14] When comparing the Annual Average Total and Average Annual Age-Adjusted Incidence Rates for Children and Adolescents of Brain and Other Central Nervous System Tumors from 2009-2013[4] and 2012-2016[12] an increase in total cases of 0-19 year olds from 23,522 to 24,931 is found, with the annual average increasing from a rate of 5.70 in 2012 to 6.06 to 2016. Thus, many scientists conclude that microwave radio frequency radiation has a significant role to play in the increasing rates of particular types of CNS cancers being reported.

A senior epidemiologist at US healthcare provider Kaiser Permanente, Dr. De-Kun Li, believes that while the increase in brain tumors is worrisome, increases in colorectal cancer is even more troubling, particularly as he believes RFR is implicated due to the manner in which people carry their smartphones in the front and back pockets of their pants and jeans. Take, for example, in 2019, the journal Cancer described a rising incidence of colorectal cancer among young Americans, with rectal cancers being slightly higher than colon cancers.[15] Another contemporary study found significant increases in colorectal cancer among people under 50 in Denmark, New Zealand, and the UK since 2009.[16] Yet another study of colorectal cancer in young adults in 20 European countries over the last 25 years found that over the last 10 years, the incidence of colorectal cancer increased 8% per year among people in their 20s, by 5% for people in their 30s, and by 1.6% for those in their 40s.[17] Dr. De-Kun Li maintains that *"When placed in trouser pockets, the phones are in the vicinity of the rectum and the distal colon and these are the sites of the largest increases in cancer."* While phones go into standby mode where telephone calls are concerned, most young people have WiFi, Bluetooth and 4G data enabled. This increases the level and incidence of exposure, as their apps keep their smartphones active on a continuous basis. Thus, other environmental, diet and lifestyle factors aside, wireless microwave radio frequency radiation is strongly implicated as a direct or indirect (e.g. co-carcinogen) in this latest 'uptick' in cancers.

Again the weight of the scientific evidence is considerable. If the findings of the above studies are accurate and generalizable, then the rates for frontal and temporal lobe tumours may increase significantly, as they more than doubled over a 20-year period in the UK, or increase in line with high RFR exposure, as RFR is now accepted as either a causal or a contributory mechanism in the occurrence of brain tumours and other cancers.

Serious questions on the trustworthiness of the report

Focusing on the report itself, and in regard to the probable deficiencies in scientific expertise among the authors of the review, the FDA has questions to answer in regard to the report's…

(a) scientific accuracy and integrity;

[13] Siegel, D. Li, S J., Henley, J., Wilson, R., Buchanan Lunsford, N., Tai, E. Van Dyne, E. (2018) Incidence rates and trends of pediatric cancer — United States, 2001–2014, American Society of Pediatric Hematology Oncology Conference, Centers for Disease Control and Prevention, Atlanta, Georgia, United States http://aspho.org/uploads/meetings/2018annualmeeting/Abstracts_for_Website.pdf

[14] Ostrom, Q. T., Gittleman, H., Truitt, G., Boscia, A., Kruchko, C., & Barnholtz-Sloan, J. S. (2018). CBTRUS statistical report: primary brain and other central nervous system tumors diagnosed in the United States in 2011–2015. Neuro-oncology, 20(suppl_4), iv1-iv86.

[15] Virostko, J., Capasso, A., Yankeelov, T. E., & Goodgame, B. (2019). Recent trends in the age at diagnosis of colorectal cancer in the US National Cancer Data Base, 2004-2015. Cancer.

[16] Araghi, M., Soerjomataram, I., Bardot, A., Ferlay, J., Cabasag, C. J., Morrison, D. S., ... & Engholm, G. (2019). Changes in colorectal cancer incidence in seven high-income countries: a population-based study. The Lancet Gastroenterology & Hepatology, 4(7), 511-518.

[17] Vuik, F. E., Nieuwenburg, S. A., Bardou, M., Lansdorp-Vogelaar, I., Dinis-Ribeiro, M., Bento, M. J., ... & Suchanek, S. (2019). Increasing incidence of colorectal cancer in young adults in Europe over the last 25 years. Gut, gutjnl-2018.

(b) systematic distortion and misrepresentation of the findings of peer-reviewed studies in reputable journals;

(c) dismissal of scientific evidence on spurious "limitations" grounds;

(d) bias and systematic omission of studies;

(e) incorrect and misleading statements;

(f) lack of transparency.

In the round, and in my view as a scientist, this review fails to meet the basic criteria set for valid and reliable scientific research. You might ask where is the objective proof of my assertion? In answering this, I contend that if a truly independent group of scientists conducted an equally rigorous review of the same literature and came to different conclusions then this would support my argument as to the trustworthiness of your report. Was there such a review? Yes, there was. I now discuss this.

The WHO's IARC Advisory Group comes to different conclusions using the same body of evidence

In March 2019, based on what was similar laboratory and epidemiological research evidence, an Advisory Group of 29 scientists from 18 countries recommended that non-ionizing radiofrequency radiation (RFR) receive High Priority from by the WHO's International Agency for Research on Cancer (IARC) Monographs programme during 2020–24. In doing so, the Advisory Group voiced concern about the health risks identified by the research they reviewed over the past 8 years, since non-ionizing radiofrequency radiation was classified as Class 2B carcinogen (see below[18]). Above I identified recent epidemiological studies on the incidence of primary brain and other central nervous system tumors and colorectal cancers in young adults, which would only serve to strengthen their recommendations, had they been available at the time of the reveiw. These studies indicate clear risks to adolescents and young adults from smartphone use and the global practice of carrying smartphones in front and back pants/jeans pockets, all things considered.

In addition, there is an increasing body of independent analyses of peer-reviewed scientific research, which concludes that non-ionizing RFR should be reclassified as a Class 1 carcinogen.[19, 20, 21, 22] It is more likely, however, that the IARC Advisory Group recommendation will result in RFR achieving at least a Class 2A probable carcinogen status. However, former ICNIRP scientist James C. Lin[23] argues in relation to the NTP and Ramazini Institute peer-reviewed findings in 2018: *"The time is right for the IARC to upgrade its previous epidemiology based classification of RF exposure to higher levels in terms of the carcinogenicity of RF radiation for humans. Recently, two relatively well-conducted RF and microwave exposure studies employing the Sprague–Dawley strain of rats—without, however, using any cancer-promoting agents (or cocarcinogens)—showed consistent results in significantly increased*

[1818] https://www.iarc.fr/news-events/report-of-the-advisory-group-to-recommend-priorities-for-the-iarc-monographs-during-2020-2024/
https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities_2020-2024.pdf.

[19]Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. Toxicology Letters.

[20] Miller, A. B., Morgan, L. L., Udasin, I., & Davis, D. L. (2018). Cancer epidemiology update, following the 2011 IARC evaluation of radiofrequency electromagnetic fields (Monograph 102). Environmental research, 167, 673-683.: //www.sciencedirect.com/science/article/pii/S0013935118303475

[21]Belpomme, D., Hardell, L., Belyaev, I., Burgio, E., & Carpenter, D. O. (2018). Thermal and non-thermal health effects of low intensity non-ionizing radiation: An international perspective. Environmental Pollution, 242, 643-658.

[22] Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. Toxicology Letters.

[23] James C. Lin is Professor of Physiology and Biophysics University of Illinois, Chicago.

total primary cancer or overall tumor rates in animals exposed to RF radiation." [24] Thus, for all intents and purposes, respected independent scientists are of the strong opinion that RFR is at least a Class 2A probable carcinogen and, given the recent experimental and epidemiological evidence, almost certainly a Class 1 carcinogen. It is also noteworthy that Professor Lin's assessment of the validity and reliability of the NTP and Ramazzini studies also calls into question the conclusions of the report by your Center.

FDA's confused and contradictory approach to regulating carcinogens

During the second half of 2019, the FDA investigated "*the detection of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications, commonly known by the brand name Zantac*." [25] In an update to its previous announcement, the FDA *"advised companies to recall their ranitidine if testing shows levels of NDMA above the acceptable daily intake (96 nanograms per day or 0.32 parts per million for ranitidine)."* N-nitrosodimethylamine (NDMA) is an IARC Class 2A probable carcinogen. That FDA recall affects Zantac and all medications containing ranitidine as NDMA was found in these over-the-counter indigestion drugs. In October, *Scientific American* published an article titled: *What We Know about the Possible Carcinogen Found in Zantac*. *Scientific American* reported that the NDMA found in this medication is classified as a probable human carcinogen based on results from laboratory tests on rats. There is little evidence that it causes cancer in humans, despite the WHO's IARC classification of it as a Class 2A carcinogen. Please note that the majority of Class 2A/B carcinogens are linked with an increased risk of cancer in individuals that are periodically exposed to them. That is, the frequent ingestion of NDMA over a particular period of time increases the risk, but not the certainty of developing cancer. Digestion remedies such as Zantac were nevertheless withdrawn because of *"fears it contains traces"* of NDMA.

To reiterate, while currently a Class 2B carcinogen as indicated above, scientific evidence and expert opinion currently places RFR in the Class 2A category and probably in the Class 1 category. The WHO/IARC is expected to reclassify it as such soon. With the proliferation of 4G, WiFi and 5G, adults and children are exposed to a scientifically recognized toxin and carcinogen, 24 hours a day, 7 days a week, from multiple sources in the home, school, the workplace, and society. The FCC and ICNIRP thermal safety levels do not protect adults or children from exposure to this carcinogen and the risks it poses. Risks much greater than that which NDMA poses in Zantac. Note that the risk here from RFR is systemic and individual, not just individual as in the case of Zantac, and is one that must be mitigated by minimizing or eliminating exposure, where possible. Thus, the FDA has demonstrated that it does not really understand the risks that carcinogens such as RFR pose to humans.

Why were the authors of the FDA review not named?

As indicated previously, it is most troubling that this report has no authors. On the FDA website on the scientific integrity page, the following text appears.

"Our scientific experts may hold differing views on what they conclude from data. There may be multiple options that can be considered during policy development or regulatory decision-making. However, in reaching our conclusions through a deliberative scientific process, FDA strives to present an evaluation and analysis of the data—including uncertainties—in an unbiased manner."[26]

[24] Lin, J. C. (2019). The Significance of Primary Tumors in the NTP Study of Chronic Rat Exposure to Cell Phone Radiation [Health Matters]. IEEE Microwave Magazine, 20(11), 18-21.

[25] https://www.fda.gov/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs

[2626] https://www.fda.gov/science-research/about-science-research-fda/scientific-integrity-fda

In light of the report's provenance and lack of transparency in its authorship and conduct, the following questions require attention.

- Did the in-house scientific experts at the FDA's Center for Devices and Radiological Health (CDRH) refuse to be associated with the published conclusions?
- How can the scientific community accept the validity and reliability of an anonymous report, given its mysterious provenance?
- How are we to evaluate any conflicts of interest among the authors of the report?

It is notable that as Director of the Center for Devices and Radiological Health, you have not put your name to this report nor signed off on it, as one would have expected. *Why is this?*

There are too many question marks over this report for it to be accepted as valid and reliable by any reasonable person, let alone a member of the scientific community. Thus, one may ask if the FDA has failed in its statutory duty to protect public health by promulgating the falsehood that RFR is not a carcinogen? Has it, therefore, put the health of US citizens, and children in particular, at significant risk, the very antithesis to its overall mission to *"protect the public health"*?

Yours Sincerely,

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Statements to the FDA by Alfonso Balmori, BSc, Lennart Hardell MD, Paul Heroux PhD, Devra Davis PhD, Elihu D. Richter MD, MPH, Alvaro de Salles, PhD, Dr. Marc Arazi, Marko S. Markov PhD, Martin L. Pall, PhD, Hiie Hinrikus, PhD, DSc, David O. Carpenter MD, Suleyman Dasdag PhD.

Statement by Wildlife Biologist Alfonso Balmori, BSc on the FDA Review of Cell Phone Radiation and Cancer

The FDA review omits an evaluation of the science on wireless radiation impacts to trees and wildlife. Electromagnetic radiation is a form of environmental pollution which may hurt wildlife. I am providing examples of my published research below as examples of this scientific evidence.

I have co-published research entitled "Radiofrequency radiation injures trees around mobile phone base stations" finding harm to trees near base stations (cell antennas) in a long term field monitoring study in two cities. We measured the radiofrequency radiation levels and found significant differences between the damaged side facing the cell phone mast and the opposite side. Our statistical analysis demonstrated that electromagnetic radiation from mobile phone masts was harmful to the trees. The damage usually starts on one side of the tree, then extends to the whole tree over time. https://www.ncbi.nlm.nih.gov/pubmed/27552133

I have also published an experimental study where we exposed eggs and tadpoles of the common frog (Rana temporaria) to the electromagnetic radiation from mobile (cell) phone antennas located at a distance of 140 meters. The experiment lasted two months, from the egg phase until an advanced phase of tadpole prior to metamorphosis. In this study, we found the exposed group had altered development and a higher mortality rate in comparison to the unexposed frogs. https://www.ncbi.nlm.nih.gov/pubmed/20560769

In addition, my research has documented anthropogenic radiofrequency electromagnetic fields as an emerging threat to wildlife orientation. For example, exposure at levels that are found in the environment (in urban areas and near base stations) may particularly alter the receptor organs to orient in the magnetic field of the earth. These results could have important implications for migratory birds and insects, especially in urban areas, but could also apply to birds and insects in natural and protected areas where there are powerful base station emitters of radio frequencies. Therefore, more research on the effects of electromagnetic radiation in nature is urgently needed to investigate this emerging threat. At the present time, there are reasonable grounds based on scientific evidence for believing that microwave radiation constitutes an environmental and health hazard. Existing guidelines are not protective. The paper "Anthropogenic radiofrequency electromagnetic fields as an emerging threat to wildlife orientation" is online at https://www.ncbi.nlm.nih.gov/pubmed/25747364

Another research study I co-published in the journal Electromagnetic Biology and Medicine is entitled "The urban decline of the house sparrow (Passer domesticus): a possible link with

electromagnetic radiation." Between October 2002 and May 2006, point transect sampling was performed at 30 points during 40 visits in Valladolid, Spain. At each point, we carried out counts of sparrows and measured the mean electric field strength (radio frequencies and microwaves: 1 MHz–3 GHz range). Significant declines (P = 0.0037) were observed in the mean bird density over time, and significantly low bird density was observed in areas with high electric field strength. The logarithmic regression of the mean bird density vs. field strength groups (considering field strength in 0.1 V/m increments) was R = −0.87 (P = 0.0001). The results of this article support the hypothesis that electromagnetic signals are associated with the observed decline in the sparrow population. We conclude that electromagnetic pollution may be responsible, either by itself or in combination with other factors, for the observed decline of the species in European cities during recent years. The apparently strong dependence between bird density and field strength according to this work could be used for a more controlled study to test the hypothesis. https://www.ncbi.nlm.nih.gov/pubmed/17613041
In another study, monitoring of a white stork population in the vicinity of Cellular Phone Base Stations was carried out, with the objective of detecting possible effects. The total productivity, in the nests located within 200 meters of antennae, was 0_86 ± 0_16. For those located further than 300m, the result was practically doubled, with an average of 1_6 ± 0_14. Very significant differences among the total productivity were found (U = 240_ p = 0_001, Mann-Whitney test). Twelve nests (40%) located within than 200m of antennae never had chicks, while only one (3.3%) located further than 300m had no chicks. The electric field intensity was higher on nests within 200m (2_36 ± 0_82V/m) than on nests further than 300m (0_53 ± 0_82V/m). The study concludes that, "these results are compatible with the possibility that microwaves are interfering with the reproduction of white storks and would corroborate the results of laboratory research by other authors". https://www.tandfonline.com/doi/abs/10.1080/15368370500205472

A review on the impact of radiofrequency radiation from wireless telecommunications on wildlife is presented in "Electromagnetic pollution from phone masts. Effects on wildlife" published in the journal Pathophysiology. Electromagnetic radiation is a form of environmental pollution which may hurt wildlife. Phone masts located in their living areas are irradiating continuously some species that could suffer long-term effects, like reduction of their natural defenses, deterioration of their health, problems in reproduction and reduction of their useful territory through habitat deterioration. Electromagnetic radiation can exert an aversive behavioral response in rats, bats and birds such as sparrows. Therefore microwave and radiofrequency pollution constitutes a potential cause for the decline of animal populations and deterioration of health of plants living near phone masts. To measure these effects urgent specific studies are necessary.
https://www.ncbi.nlm.nih.gov/pubmed/?term=Electromagnetic+pollution+from+phone+masts.+Effects+on+wildlife

Despite the widespread use of wireless telephone networks around the world, authorities and researchers have paid little attention to the potential harmful effects of mobile phone radiation on wildlife. This paper briefly reviews the available scientific information on this topic and recommends further studies and specific lines of research to confirm or refute the experimental

results to date. Controls must be introduced and technology rendered safe for the environment, particularly, threatened species. https://www.ncbi.nlm.nih.gov/pubmed/25089692
Atmospheric electrical discharges during thunderstorms, and the related electromagnetic fields (EMFs)/waves called sferics, can be sensed by humans at long distances through a variety of symptoms, mainly headache, fatigue, etc. Up to today there is no explanation for this association. Sferics consist of partially polarized electromagnetic pulses with an oscillating carrier signal in the very low frequency (VLF) band and a pulse repetition frequency in the extremely low frequency (ELF) band. Their ELF intensity may reach ~5 mV/m at global ranges, and ~0.5 V/m at ~1000 km from the lightning. The health symptoms associated with sferics are also associated with antennas of mobile telephony base stations and handsets, which emit radio frequency (RF) radiation pulsed on ELF, and expose humans at similar or stronger electric field intensities with sferics. According to the Ion Forced-Oscillation mechanism, polarized ELF EMFs of intensities down to 0.1–1 mV/m are able to disrupt any living cell's electrochemical balance and function by irregular gating of electro-sensitive ion channels on the cell membranes, and thus initiate a variety of health symptoms, while VLF EMFs need to be thousands of times stronger in order to be able to initiate health effects. We examine EMFs from sferics in terms of their bioactivity on the basis of this mechanism. We introduce the hypothesis that stronger atmospheric discharges may reasonably be considered to be ~70% along a straight line, and thus the associated EMFs (sferics) ~70% polarized. We find that sferics mainly in the ELF band have adequate intensity and polarization to cause biological/health effects.

We provide explanation for the effects of sferics on human/animal health on the basis of this mechanism. https://www.ncbi.nlm.nih.gov/pubmed/28558424
It is documented that a few days or weeks before major Earthquakes (EQs) there are changes in animal behavior within distances up to 500 km from the seismic epicenter. At the same time Seismic Electric Signals (SES), geomagnetic and ionospheric perturbations, are detected within similar distances. SES consist of single unipolar pulses, and/or groups of such pulses called "SES activities" with an average frequency between successive pulses on the order of ~0.01 Hz and electric field intensity on the order of ~10-5-10-4 V/m (Frazer-Smith et al., 1990; Rikitake, 1998; Varotsos et al., 1993, 2011, 2019; Hayakawa et al., 2013; Grant et al., 2015). We show that the SES activities can be sensed by living organisms through the "Ion Forced-Oscillation Mechanism" for the action of Electromagnetic Fields (EMFs) on cells, according to which polarized EMFs can cause irregular gating of electro-sensitive ion channels on the cell membranes with consequent disruption of the cell electrochemical balance (Panagopoulos et al., 2000, 2002, 2015). This can be sensed by sensitive animals as discomfort in cases of weak and transient exposures, and may even lead to DNA damage and serious health implications in cases of intense exposure conditions (as in certain cases of man-made EMF exposures). Moreover, we show that the geomagnetic and ionospheric perturbations cannot be sensed through this mechanism. The same mechanism has explained meteoropathy, the sensing of upcoming thunderstorms by sensitive individuals, through the action of the EMFs of lightning discharges (Panagopoulos and Balmori, 2017). The present study shows that centuries-long anecdotal rumors of animals sensing intense upcoming EQs and displaying unusual behavior, lately documented by systematic studies, are now explained for the first time on the basis of the

electromagnetic nature of all living organisms, and the electromagnetic signals emitted prior to EQs. https://www.ncbi.nlm.nih.gov/pubmed/28558424

Signed, Alfonso Balmori, BSc Biologist. Spain
Alfonso Balmori on researchgate.

Paul Heroux PhD Statement in Response to the FDA Report on Cell Phone Radiation

The FDA Report stated," We do not know if there is a causal effect or if these results are due to weakening of the immune response due to animal stress from cyclic heating and thermoregulation decline in aging animals leading to whole-body temperature increase, possible sleep disruption due to the cyclic heating, or due to an RF-specific effect that has not been identified and has an adverse effect before heating becomes the dominant safety issue."

Response by Paul Heroux PhD
"FDA is pushing red herrings to avoid the inevitable conclusion that electromagnetic fields have important carcinogenic effects on animals below thermal levels.

This is an apparent attempt to confuse the discussion by invoking an "immune" mechanism driven by heat and sleep disturbances, and other ghost mechanisms that would inevitably turn out to be dead ends.

These surprising comments should not distract us from (1) at least four previous spectacular animal experiments linking fields to cancer, from (2) the drastic action of fields on human cancer cells at field intensities nowhere near the thermal limit, as well as (3) the literature linking fields to reactive oxygen species and mutations.

An institution (FDA) displaying such a fundamental reluctance to acknowledge evidence should abstain from commenting on the NTP study.

The FDA Report stated," It is possible that any form (ambient, IR, ultrasound) of cyclic whole-body heating of this magnitude may cause similar findings, but no such studies have been conducted to date."

Response by Paul Heroux PhD
"This is a way to extend the lie about health impacts of electromagnetic fields by directing attention to some form of further investigation that would allow industry to proceed with increases in human exposures, while we await the results of yet another waste of time."

Paul Héroux, PhD
Professor of Toxicology and Health Effects of Electromagnetism
McGill University Medicine

Department of Surgery, McGill University Health Center

Statement by Christos D. Georgiou, Ph.D.

The issued by FDA "literature review" conclusion that there are no connections between cell phones and cancer is not valid, as it is contradicted, at least, by the classification, by IARC-WHO, of cell phone-emitted EMF as possibly carcinogenic to humans (Group 2B). The numerous research studies IARC reviewed to base the Group 2B classification also included a study of mine (cited in the IARC-WHO 2013 report; https://www.ncbi.nlm.nih.gov/books/NBK304630/pdf/Bookshelf_NBK304630.pdf, pages 101,103,121), which advances the free radical pair mechanism of non thermal induction of carcinogenic oxidative stress by exposure to low-intensity RF radiation.

Christos D. Georgiou, Ph.D.
Professor Emeritus of Biochemistry
Biology Department
University of Patras, Greece

Statement by Anthony B. Miller MD

“Radiofrequency is an established carcinogen. Cell phones held close to the head will substantially increase the risk of a type of brain cancer—glioblastoma,” stated Dr. Anthony B. Miller, Professor Emeritus at the Dalla Lana School of Public Health, University of Toronto and former Director of the Epidemiology Unit of the National Cancer Institute of Canada. Miller also served as a Senior Epidemiologist, International Agency for Research on Cancer and published a major research review in 2018, concluding that “based on the evidence reviewed it is our opinion that IARC's current categorization of RFR as a Possible Human Carcinogen (Group 2B) should be upgraded to Carcinogenic to Humans (Group 1). Miller recommends people use safer wired technology rather than wireless technology, “We should do all we can to reduce exposure.”

Statement by Devra Davis PhD

“This astonishing report from an agency charged with protecting public health should be retracted. It does not meet minimum standards of scientific reporting or review, as it takes a skewed look at science, lists neither authors nor reviewers. It ignores the recent Yale study supported by the American Cancer Society linking cell phone use to thyroid cancer. It does not consider that antiquated phone test methods do not protect anyone from microwave radiation emitted by phones or other devices. It ignores repeated calls from the American Academy of Pediatrics and numerous experts in the field of child health to take into account the unique vulnerability of children, pregnant women and young adults. No reference is made to a growing body of research showing brain damage and headache and replicated research showing

memory damage in teens after just one year of cell phone use," stated Devra Davis PhD, MPH, President of the Environmental Health Trust.

Prof. Suleyman Dasdag, Department of Biophysics, Medical School of Istanbul Medeniyet University, Istanbul,Turkey, also noted: "Mobile phones are not as innocent as they seem. In my studies to date, I have found that wireless radiofrequency (RF) does not affect every organ in the same way and very different parameters are important in the emergence of effects. In our two studies on RF and the brain in 2015 and our study published this year, we found that RFs may affect key molecules. In addition, we observed in our brain study that RF radiation can affect the death of brain cells. I also want cell phones not to cause brain tumors, but our studies and the published studies we have reviewed are in the direction that the risk will increase even more after 5G."

Martin L. Pall, PhD, Professor Emeritus of Biochemistry and Basic Medical Sciences, Washington State University who has published extensively on how EMFS activate Voltage-Gated Calcium Channels which can lead to tumor promotion, disputed the report's conclusions that cellphones are safe, noting that, "EMFs produce double strand DNA breaks which cause cancer via chromosomal rearrangements, copy number mutations and gene-amplification. EMFs also cause oxidized bases including 8-OHdG, which produce transition and transversion mutations such that when these occur in oncogenes or tumor suppressor genes, these mutations have important roles in causing cancer."

"This report is pure nonsense! It is as though the author didn't read any of the literature they cite," stated David O. Carpenter MD, Director, Institute for Health and the Environment, University at Albany who has repeatedly documented adverse effects over 4 decades of published research.

"Radiofrequency radiation should be regarded as a human carcinogen causing glioma, "stated Lennart Hardell MD, an advisor to the World Health Organization's International Agency for Research on Cancer, who has published several studies finding associations between cancer and people who use cell phones regularly. He referred to one of his published research reviews concluding that radiofrequency is a carcinogen.

"The latest report by the National Toxicology Program is a game changer. We also should not ignore case series reports on cancer in military workers with whole body exposure to RF/MW, stated Professor Elihu D. Richter MD, MPH at the Occupational and Environmental Medicine Department at the Hebrew University-Hadassah School of Public Health and Community Medicine.

"Due to the recent results described in many peer reviewed scientific papers published in the international literature showing significant human health risks (including cancer) at levels of EMF exposures well below the available recommended limits (e.g., ICNIRP, FCC/IEEE/ANSI). We believe that the Precautionary Principle should be urgently adopted and the population

should be fully informed on the best ways to reduce their exposure and health impacts, “ stated Alvaro de Salles, Ph. D. Professor at Federal University of Rio Grande do Sul, Porto Alegre, Brazil whose research studies have found children are more exposed to RF from cell phones.

"The FDA's position is totally incomprehensible especially since the findings of the Phonegate scandal have revealed the deception by cell phone manufacturers who have knowingly overexposed all cell phone users to excessive radiation for decades," stated Dr. Marc Arazi of Phonegate Association.

"Mankind is being forced to participate in a giant "experiment" without protocol, without collection of data and without adequate evaluation of the cocktail of EMF humankind is exposed to every day. The engineering community needs to recognize the fact that there is a difference between experimental exposure and continuous exposure to multiple frequencies and modulations. The FDA as well as ICNIRP have failed to investigate this to assure public safety, " stated Marko S. Markov PhD, author of major medical textbooks in bioelectromagnetics.

“Tissue heating is certainly not the only effect caused by radiofrequency radiation.,” stated Hiie Hinrikus, PhD, DSc, Professor Emeritus Centre for Biomedical Engineering at the Tallinn University of Technology who has published several research studies on microwave radiation. “Hundreds of studies performed by independent researchers have convincingly approved biological effects caused by low-level radiofrequency radiation in animals and humans at constant temperature. The reason is coherent nature of radiofrequency radiation. During billions years, living nature has been adapted to natural solar radiation, radiofrequency radiation is in principle different from solar radiation. Sun emits irregular incoherent radiation in wide frequency spectrum whereas technical radiofrequency sources emit regular coherent single-frequency radiation. The impact of irregular random and regular coherent electromagnetic radiation on living systems is different. Irregular radiation causes random forces and movement in tissues and can create only tissue heating. Coherent radiation causes regular forces and synchronous movement affecting simultaneously large amounts of molecules and cells in tissues. Therefore, the impact of radiofrequency radiation is much stronger than the heating effect only. This is convincingly approved also in microwave chemistry.”

From: Kassiday, Daniel F. H. <Daniel.Kassiday@fda.hhs.gov>
To: 'theodorams@aol.com' <theodorams@aol.com>
Cc: O'Hara, Michael D <Michael.OHara@fda.hhs.gov>; Jung, William <William.Jung@fda.hhs.gov>; Ochs, Robert <Robert.Ochs@fda.hhs.gov>; CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: RE: Please respond to my follow up questions on wireless radiation
Date: Wed, May 31, 2017 12:21 pm

I apologize for the delay.

Your Follow up Questions To The FDA in blue
FDA answers to follow up questions are in red

I asked:**Will the FDA be updating it's website to include the NTP study results on radiofrequency radiation?**
The FDA answered:Our conclusion that current radiofrequency (RF) exposure limits adequately protect the public health has not changed based on the draft National Toxicology Program (NTP) report about a portion of NTP's study. We do not anticipate a website update on the NTP study before NTP publishes a final report regarding the complete study.

My Follow Up Question 1. : The results on the brain and heart cancers are final. They are not a draft In addition the research showing a genotoxic effect are now being added to the report. Even if all the other findings show "no effect" this is a significant finding. Why is the FDA waiting when children and pregnant women are actively exposing themselves to this radiation unaware that they could be racking up hours of exposure.

FDA answer to Follow-up Question 1: The results of the NTP study have not been published as a final document for the partial experiment discussed publically by the NTP nor have they been peer reviewed in the literature. Likewise, the genotoxicity experiments have also not been released publicly nor have they been peer reviewed. The data that has been released by the NTP is only a small subset of a much larger study. While the results add to the body of data on this topic they are not evidence that there is any risk of adverse health effects when exposures are at or below current exposure limits. When we have evidence of a public health hazard or significant risk, FDA has not hesitated to issue and disseminate appropriate safety notices. Our conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 2. Please explain how the FDA arrived at that conclusion?

FDA Answer to Follow-up Question 2: While the experiments are interesting and well performed, the results are not clear and conclusive when compared to whole body or partial body RF exposures that comply with the existing safety limits. The lowest whole body RF exposures tested in the NTP experiment are much higher than the allowable whole body exposure limit. There are differences between the experimental controls and the historical controls that further limit the conclusions reached. Our conclusion that the current RF exposure limits adequately protect the public health is not altered by the available information related to the NTP study.

Why is the FDA not considering the evidence showing fertility damage from wireless and cellphones? Specifically the research on impacts on sperm DNA at non thermal levels, impacts on the ovaries and the fact that the NTP study found the exposed group had offspring with lower birth weight. See research study found here in the drop down: http://ehtrust.org/science/research-on-wireless-health-effects/
We have looked at the papers you identified. Those studies suffer from many confounding factors that significantly limit or eliminate their impact. There is insufficient evidence available to establish adverse health effects, including when these studies are taken into account.

My Follow Up Question 3. So you are stating that all these studies are insufficient. On what grounds?

FDA Answer to Follow-up Question 3 part 1: Peer-reviewed papers are evaluated for any adverse effects reported to be caused by RF exposure. The relative strength of those papers' conclusions must be considered. Examples of factors that may weaken the utility of a paper include: the study design, study protocol violations, RF exposure sources, the dosimetric methods, SAR determination, thermometry, reproducibility of RF emissions, reproducibility of all environmental factors (temperature, air flow, vibration, etc.), differences with historical controls and recall bias. Based on the individual papers and analysis by expert review panels we conclude that the current RF exposure limits adequately protect the public health. This includes reproductive health.

What do you think of this study please in particular as the majority of studies showed an effect.
Houston B., et al. "The effects of radiofrequency electromagnetic radiation on sperm function." Reproduction, 2016.

- Among a total of 27 studies investigating the effects of RF-EMR on the male reproductive system, negative consequences of exposure were reported in 21. Within these 21 studies, 11 of the 15 that investigated sperm motility reported significant declines, 7 of 7 that measured the production of reactive oxygen species documented elevated levels and 4 of 5 studies that probed for DNA damage highlighted increased damage, due to RF-EMR exposure. Associated with this, RF-EMR treatment reduced antioxidant levels in 6 of 6 studies that studied this phenomenon, while consequences of RF-EMR were successfully ameliorated with the supplementation of antioxidants in all 3 studies that carried out these experiments.

FDA Answer to Follow-up Question 3 part 2 – re: Houston et al: Thank you for directing us to the Houston et al. "The effects of radiofrequency electromagnetic radiation on sperm function" review paper. We find this scientific opinion of this review paper to be interesting and the tabulation of the available data from the cited references useful. The paper does not extensively cover the confounding factors present in the papers reviewed. This appears to be because it is a review article that's purpose is the development of a possible mechanism of action. The authors stated that, "we explored the documented impact of RF-EMR on the male reproductive system and considered any common observations that could provide insights on a potential mechanism". The authors also acknowledge that research to date is not conclusive. In their conclusion, they say, "to date, contradictory studies surrounding the impact of RF-EMR on biological systems maintain controversy over this subject". The review's authors' proposed two-step mechanism of action and their call for further laboratory research are interesting. While the opinion of the authors contributes to the body of knowledge on this topic it alone does not change the current understanding of mechanism of RF action nor does it prove there is an adverse effect of RF exposure that complies with the limits on male reproduction. The current RF exposure limit adequately protects the public health.
Additionally, a recent paper by Lewis adds some epidemiological evidence that there is no adverse effect from RF exposures from cell phones. Please see, Lewis, R. C., et al. (2017). "Self-reported mobile phone use and semen parameters among men from a fertility clinic." Reprod Toxicol 67: 42-47. Lewis et al concluded, "The present study found that within the range of self-reported mobile phone use there was no evidence for a relationship with semen quality."

What are the confounding factors on this study please.
Avendaño C, Mata A, Sanchez Sarmiento CA, Doncel GF.(2012). Use of laptop computers connected to internet through Wi-Fi decreases human sperm motility and increases sperm DNA fragmentation. Fertility Sterility. 97(1), 39-45.

FDA Answer to Follow-up question 3 part 3: The paper Avendano et al. examines the impact of radiofrequency radiation from an internet-connected laptop on human sperm in vitro. The authors test an interesting hypothesis with inventive methods. The experiment suffers from a lack of radiofrequency field homogeneity, inadequate information regarding occurrence of temperature change, ambiguity regarding if the control was handled the same as the exposed samples, and some of the semen samples were teratozoospermic which may have impacted the conclusions. The use of a reproducible source of RF exposure is essential to assure that reproduction of an experiment is possible. Cell phones, Wi-Fi routers, and laptops are not reproducible sources of RF exposure thus should not be used for experimentation.

This conclusion is consistent with recent expert reports on radiofrequency. For example, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015 concluded, "The previous SCENIHR Opinion concluded that there were no adverse effects on reproduction and development from RF fields at non-thermal exposure levels. The inclusion of more recent human and animal data does not change that assessment. Therefore, it is concluded that there is a strong overall weight of evidence against an effect of low-level RF fields on reproduction or development."[2]

My Follow Up Question 4. Is the FDA's stance to consider the SCENIHR opinion as the FDA's opinion?

FDA answer to Follow-Up Question 4: No, the SCENIHR expert working group is composed of expert scientists that have reviewed, reported on, and collated a large amount of information on RF radiation and FDA values their contribution. However, the FDA comes to its own conclusions.

My Follow Up Question 5. What review has the FDA done on fertility research. Please document and share this analysis.

Regarding your particular concern related to body weight, the NTP's draft report states, "Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation.[3]"

FDA Answer to Follow-Up Question 5: We follow the potential radiofrequency bioeffects literature. We are not actively engaged in laboratory or clinical fertility research. However, there may be other parts of the FDA that does research fertility.

My Follow Up Question 6. Please see on Page 8 the following:

- RESULTS
- In pregnant rats exposed to 900 MHz GSM- or CDMA-modulated RFR, no exposure-related effects were observed on the percent of dams littering, litter size, or sex distribution of pups. Small, exposure-level-dependent reductions (up to 7%) in body weights compared to controls were observed throughout gestation and lactation in dams exposed to GSM- or CDMA- modulated RFR. In the offspring, litter weights tended to be lower (up to 9%) in GSM and CDMA RFR-exposed groups compared to controls. Early in the lactation phase, body weights of male and female pups were lower in the GSM-modulated (8%) and CDMA-modulated (15%) RFR groups at 6 W/kg compared to controls. These weight differences in the offspring for both GSM and CDMA exposures tended to lessen (6% and 10%, respectively) as lactation progressed. Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation n in all groups of male rats exposed to GSM-modulated RFR

The quote you sent me is not adequate to address the concern I raised. As you can see from this paragraph, the weights were lower (see my yellow highlighted areas above) after prenatal exposure. You sent me details that pertain to the animals later in the study. (My daughter was a low birth weight when she was born and has caught up now.) The fact is that an effect of lower birth weight was found at non thermal levels. This indicates an important non thermal effect. (Smoking caused babies to be smaller as well and the industry stated this was good for mothers and doctors recommended that women smoke if they were gaining to much weight during pregnancy.) Please explain why the FDA is not considering this effect and investigating the issue. Clearly non-thermal effects are evident from this study. Please explain the FDA's analysis on the issue of these lower body weights.

FDA Answer to Follow-up question 6: FDA is sorry that our quote was not adequate to address your concern. However, our quote is still accurate. The observation of a birth weight difference between exposed and control-animals is an important observation. The excerpted discussion above does say that pregnant rats gave birth to normal litters, pup were smaller early in lactation and lessened as lactation proceeded and no differences were noted in weight during the remainder of the chronic study. The very next paragraph discussed in the study said that control male rat survival was lower than RF exposed rat survival. This survival advantage for RF exposed

male rats also may suggest that the lower birth weight at birth was not significant in the exposed group. We do not believe that this is a non-thermal effect of radiofrequency exposure. The study also said that thermal regulation was more difficult in pregnant or geriatric rats. It is possible that temperature elevation and thermal regulation was still an issue in these whole body irradiation experiments.

Is it still the FDA's position that the weight of evidence does not show health effects? If so, please provide the documentation that supports this position by the FDA in light of the NTP results. In a prior email dated February 5, 2016 Email RE-Question about the FDA and radiofrequency radiation this is what you told me. Please provide the scientific research that shows safety.

The FDA's position has not changed. Based on the available scientific evidence, including published literature and published expert reports, the Agency has concluded that the current RF exposure limits provide adequate protection for use of RF consumer communication electronic products like cell phones.

My Follow Up Question 7. Please send me the "the available scientific evidence, including published literature and published expert reports" the FDA specifically looked at to state that "the Agency has concluded that the current RF exposure limits"

FDA Answer to Follow-up question 7: Copyright infringement is a problem with this request. What you are asking for is already on line at the WHO website, SCENIHR website, in the bibliographies of the documents noted in our original response and through PubMed literature searches.

Many expert reports have been released that discuss the strengths and weaknesses of the published literature. There have also been formal analyses and reviews of published expert reports.

You cite two reviews but is this how the FDA investigates ? by citing two reviews well cited by industry funded scientists? It is notable that this review "International and national expert group evaluations: biological/health effects of radiofrequency fields." not only cites industry linked reports but the authors state: "We thank Chung-Kwang Chou (chairman, SC-95 of the international committee on electromagnetic safety, Institute of Electrical and Electronic Engineers) for critical reading of the manuscript and helpful suggestions." CKChou is former Chief Motorola Scientist.

My Follow Up Question 8. Are these reviews that you refer to from organization that the FDA then is taking on as it's own opinion? How does the FDA determine that these reviews are scientifically sound and unduly influenced by industry?

FDA Answer to Follow-up Question 8: The FDA has been following RF exposure potential bioeffects since at least the early 1990s. We have met with and listened to numerous organizations on the topic, including your organization. The FDA reviews all published papers and reviews that are brought to our attention or that we identify through literature searches. Our answers were meant to guide you to scientific reviews that cover a large amount of literature in a systematic fashion. The expert review groups that have reviewed the RF literature have guidance policies and procedures in place to prevent undue influence from outside. FDA knows that Chung-Kwang Chou is an internationally recognized expert on RF radiation and we know that we also know that he worked for industry. The weight of the evidence from the literature and expert opinions are what lead us to believe that the current exposure limits adequately protect the general public.

We note that Vershaeve 2012 specifically evaluated expert reports to assess bias. Verschaeve says, "**Evaluation of expert group reports based on 10 criteria**

An evaluation of the different reports should take into account a great number of aspects. Amongst them the composition of the working group, the topics that were taken into account and the methods that were used are certainly some of the important aspects. We therefore tried to identify the members or participants in the working group activities and tried to see whether they constituted a *multidisciplinary* and *independent* group of experts. Did they evaluate all scientific (peer reviewed) publications, or did they make a selection of papers, and if so, what was the rationale for doing so? Was this satisfactory? Was the report a consensus report? Where minority opinions mentioned?" Similarly, Vijayalaxmi and Scarfi 2014 included comments on negative and positive aspects of the expert groups and their reports.

Does the FDA consider oxidative stress a health effect? I sent you a review article last year about this and it seems important to share with the American people (http://nebula.wsimg.com/107f00a88ae36803a132e3ca6c222157?AccessKeyId=045114F8E0676B9465FB&disposition=0&alloworigin=1)
Thank you for the review article on oxidative stress. We have reviewed it, and it contains opinions that have added to our understanding of the topic.

In the World Health Organization (WHO) International Agency for Research on Cancer (IARC) monograph 102 (2013), the IARC expert working group concluded that there was only weak evidence that adverse health effects could be caused by RF due to oxidative stress. We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects.

My Follow Up Question 9. How do you substantiate such a statement ?
"We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects."

FDA Answer to Follow-up Question 9: From the totality of the scientific literature available and expert opinions.

My Follow Up Question 10. Does the FDA think that oxidative stress can impact health.
the research study here states that constant oxidative stress over tome can lead to health problems. Please review and explain why this has not impacted the view of the FDA.

FDA Answer to Follow-up question 10: Oxidation is a normal component of metabolism and cells have redundant systems to deal with the consequences of oxidative stress. We are aware that approximately 70% of the damage done by ionizing radiation is due to oxidative stress. We follow the RF literature on potential mechanisms of action. Our opinion at this time is that the totality of the scientific literature does not support that hazardous levels of oxidative stress can be induced by radiofrequency radiation exposure that does not also cause hazardous temperature elevation.

If the FDA is supposed to protect the public then they need to inform the public of the fine print instructions the manual related to RF. Why is the FDA not acting on this and informing people of the fine print instructions on RF on cell phones and wireless devices? Children are carrying phones on their bodies, tucked in spandex pants and in bras and jeans in school classrooms. Can you please explain why the FDA is not ensuring the public is aware of the fine print warnings?
There is a large safety factor included in the public exposure limit (see IEEE Std. C95.1-2005 Annex C, *Rationale*, for more information regarding this safety factor).

My Follow Up Question 11. What does the FDA think the safety factor is for SAR exposure limits. Please state it.

FDA Answer to Follow-Up Question 11: Wireless communication devices are required to meet radiofrequency (RF) energy exposure guidelines set forth by the Federal Communication Commission (FCC). These guidelines were last revised on August 1st, 1996 when the FCC adopted local body RF energy specific absorption rate (SAR) limits for devices operating within close proximity to the body as recommended by ANSI/IEEE C95.1-1992 guideline. The ANSI/IEEE C95.1 guidelines are based on protection from thermal effects of whole body RF energy exposure. RF exposure in the 1– 4W/kg SAR range was shown to induce behavioral changes in several animal species, including non-human primates. The observed behavioral change was accompanied by an increase in core temperature of ~1°C. ANSI/IEEE C95.1-1992 guideline derives the local body exposure limit in two steps. First the threshold for behavioral responses was set at 4W/kg SAR, and then a safety factor of 10 was put in place for exposure under controlled environmental conditions (occupational exposure). An additional safety factor of 5 was put in place for the general public exposure setting the whole body exposure limit at 0.08

W/kg. Thus the public whole body exposure limit is approximately 50 times lower than the threshold for heat related adverse health effects. Based on the general public whole body exposure limit a spatial peak limit on 1.6 W/kg averaged over one gram of tissue was set for local body exposure. Before adopting the ANSI/IEEE C95.1-1992 limits the FCC consulted with the Food and Drug Administration (FDA) and other health agencies.

We note that Federal Communications Commission (FCC) guidance on general RF exposure procedures and equipment authorization policies for mobile and portable devices explains that for devices designed to operate in contact with the body, the specific absorption rate (SAR) compliance tests should be conducted a separation distance of 5 mm or less (FCC KDB 447498 D01 section 4.2.2).

My Follow Up Question 12. Why does the FDA not share this information with the public? Why are these separation distances not stated on the FDA website so that te American people are aware of it. I have a teenage daughter and her friends do the following: They place the cell phone in their spandex pants against their skin. They lay the phone on their lap as they watch music videos or stream and facetime. They also sleep with the phone next to their head. They easily can roll over and sleep on the cell phone. Women carry cell phones in their bra all the time. The public is unaware. Again- Why does the FDA not share this information with the public on their website? So far it is a secret.

FDA Answer to Follow-up question 12: As you yourself noted, the FCC shares this information with the public. The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC.

Additionally, that FCC guidance explains that mobile and portable devices designed to be used with a body-worn accessory must be tested for body-worn accessory SAR compliance. According to the guidance, a conservative minimum test separation distance should be used for such testing, at worst case using no more than a 25 mm separation distance. The same FCC guidance states that operating manuals must include specific information to allow users to select body-worn accessories that meet the compliance test separation distance requirements, and all supported body-worn accessory operating configurations must be clearly disclosed to users, through conspicuous instructions in the user guide and user manual, to ensure unsupported operations are avoided.

My Follow Up Question 13. Everyone I have spoken to to is 100% unaware of this information buried in manuals. Please explain how the FDA has decided it is not their responsibility to inform the public on this. Has the FDA done a survey?

FDA Answer to Follow-up Question 13: The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC. As any web search for "usability of user manuals" will reveal, there is a lot of concern and research on why most consumers ignore manuals and instructions. So it is not surprising that consumers are unaware of one particular fact in a manual when most consumers don't read anything in user manuals. The FDA has not done a survey and we are not aware if the FCC has.

Additionally, cell phone RF exposure compliance testing must be determined at the maximum average power level.

My Follow Up Question 14. Well actually you will use your cell phone at maximum power under several conditions such as if you are far from a tower with lower bars- or in an elevator, in a moving car far from a tower and video streaming- as you are aware. So it is possible. Is the FDA saying that although it is possible to be at maximum power, it is not necessary for the public to be aware because it does not happen often? There are many moments when people use phones in maximum power conditions- especially when they have a lot of applications on at once far from a base station. Please explain why the FDA is rationalizing not telling people about this.

FDA Answer to Follow-up Question 14: As you state, these are *moments* when a cell phone needs to operate at maximum power. Cell phones will always attempt to operate at the minimum power necessary in order to prolong battery life. Over the course of a day the average exposure is considerably lower. You mention using a cell phone in a moving car far from a tower; because of factors unrelated to RF exposure this is indeed a dangerous situation. The safety factors set in place for RF exposure adequately protect the general public.

However, the National Safety Council estimates cell phone use to be involved in 26 percent of all motor vehicle crashes – 5 percent of crashes involve texting, while 21 percent involve drivers talking on handheld or hands-free cell phones. (http://www.nsc.org/NewsDocuments/2014-Press-Release-Archive/3-25-2014-Injury-Facts-release.pdf) Clearly the greatest risk to public safety posed by cell phones is the risk of death or injury resulting from vehicular accidents due to distracted driving.

In order to conserve battery life, cell phones seldom actually operate at maximum power, which reduces the SAR proportionately.

My Follow Up Question 15. Can you tell me what data you have on how "cell phones seldom actually operate at maximum power" How often do they opeate at maximum power.

FDA Answer to Follow-Up Question 15: There has been considerable research on cell phone power consumption related to energy management and battery life. Actually transmitted RF power can be a minor part of the power consumption in smartphones which use a lot of power for the processor and display. Unfortunately these research efforts consider total transmit power over one battery charge and do not look at a typical time history of transmission power. Actual transmit power will be dependent on many factors unique to individuals, such as: where they live and work in relation to cell phone towers and usage patterns.
There is some relevant information in IARC Monograph 102 at the bottom of page 76 and top of page 77.
There are also papers regarding exposure assessments that attempt to quantify dose for use in epidemiology assessments.

I understand that the RFIAWG was given a presentation of these findings. What is the FDA perspective on the findings now that you have reviewed them please? Please detail the next steps for the FDA with a timeline.
The U.S. Radiofrequency Interagency Working Group (RFIAWG) has not had a presentation on findings from the NTP study.

My Follow Up Question 16. Why hasn't the U.S. Radiofrequency Interagency Working Group (RFIAWG) had a presentation on these findings? I thought the Groups role was to provide some sort of oversight? Why are they not given a full presentation?

FDA Answer to Follow-up Question 16: The RFIAWG allows staff to discuss RF research and any concerns. It does not have a management or oversight role. The remainder of this question has already been answered. No further information is available.

My Follow Up Question 17. Has the FDA been given a presentation on the NTP findings of increased brain cancer, increased heart nerve sheath tumors and genotoxicity?

FDA Answer to Follow-up Question 17: The FDA has been briefed on the partial findings of the NTP study.

FDA's conclusion that current RF exposure limits adequately protect the public health has not changed based on the information in the draft NTP report about a portion of NTP's study.

My Follow Up Question 18. How did you determine that conclusion? What is the rationale for FDA's conclusions?

FDA Answer to Follow-up Question 18: From the totality of the scientific literature available and expert opinions.

When NTP completes its analysis and a full report is available, we will review it and consider what, if any, effect it has on the agency's thinking regarding risks associated with RF exposure from cell phones.

My Follow Up Question 19. Can you please explain the review process for the FDA and the transparency that will be involved in the review.

FDA Answer to Question 19: The NTP has briefed FDA on the partial result already. We believe that the NTP will also brief FDA on the completed total study when it is complete. FDA will review the entire study and decide if the results impact our understanding of its impact on RF safety.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue. What questions are being asked and of whom? What other FDA staff are involved in the process. Are any consultants working with the FDA? Who are they?
The Center for Devices and Radiological Health (CDRH) is the FDA center that regulates electronic products under the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act. Note: EPRC may also be referred to as "Radiological Health." Questions or concerns can be sent to the FDA document mail center:
U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue
WO66-5521
Silver Spring, MD 20993-0002
Marking the documents, "Attn: Division of Radiological Health" can help expedite routing to the Division of Radiological Health for review and appropriate follow-up. The staff in other divisions and offices who have the required expertise to answer specific questions are called upon for assistance when a need occurs. If necessary, we could call on expertise from other government (international, national, state, etc.) agencies, concerned consumer groups, or industry.

My Follow Up Question 20. You did not answer my questions so here they are again.
Who is the point person at the FDA for this issue and what are they doing in regards to this issue?
What questions are being asked and of whom?
What other FDA staff are involved in the process.
Are any consultants working with the FDA? If so- Who are they?

FDA Answer to Question 20: These questions have been asked and answered.

8. The NTP study found DNA damage in the brain; please detail the FDA response to these findings and the next steps in terms of protecting the people.
We assume your question is referring to the draft supplemental NTP document that covers experiments looking for DNA damage. Our conclusion that current RF exposure limits adequately protect the public health has not changed based on our review of the draft NTP supplemental papers.

The NTP comet assay, indicated DNA damage (see the table).

MALE						
Rats	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
Mice	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
FEMALE						
Rats	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
Mice	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	statistically significant trend and pairwise SAR-dependent increase					
	statistically significant trend or pairwise increase					
	no significantly different but increase in two or more groups					

My Follow Up Question 21. Please explain how this DNA damage found in the comet assay - not change the FDA opinion?

FDA Answer to Follow-up Question 21: The table you included is a variant of the table the NTP used in its briefings and is a summary of all of the Comet assay data. FDA does not agree with this summary table and how it reflects the data. Unfortunately, this paper has not been published and FDA is not at liberty to discuss the data further.

My Follow Up Question 22. What would change the FDA opinion? How much evidence is necessary?

FDA Answer to Follow-up Question 22: FDA believes that the current exposure standard is adequate to protect public health. In order to change that belief we would need to see well controlled studies that have reproducible results, we would also consider opinions from other expert organizations and the rational for or against changes by standard setting organizations that collectively say that the current exposure standards need to change to protect people.

9. Is the FDA preparing a response to inform the FCC of the official recommendations to the issue of cell phones and wireless? Please give specifics on the timelines.
As a general policy, the FDA does not comment on pending matters that are under review. If FDA had concerns regarding the current RF exposure limits, the agency would communicate those concerns to FCC.

My Follow Up Question 23. I thought that a transparent process was underway and that all comments would be available. The FCC states they are looking to their federal partners for guidance as they are not a health and safety agency. If the FDA does not give any comments then I wonder who will. Will the FDA be commenting at all to the FCC in their Proceeding Number 13-84? Have they ever commented?

FDA Answer to Follow-up Question 23: Question was asked and answered.

The FDA has received reports of people who develop headaches, nerve damage and rashes from cell phone and wireless use. What is being done by the FDA to monitor these side effects?
The FDA has received anecdotal reports from individuals that attribute their symptoms to RF exposure from cordless phones and cell phones. The anecdotal reports are reviewed to determine if they contain new information indicating that RF radiation from an electronic product caused the adverse health effects described.

No such evidence has been revealed through our review of those reports. We also monitor literature regarding experiments intended to prove or disprove a causal link between RF exposure and adverse health effects as well as literature regarding the most effective treatments for individuals suffering from these symptoms.

Where can these reports be accessed online?

Currently, these reports cannot be publicly accessed online.

My Follow Up Question 24. Why not, Can you please make them available.

FDA Answer to Follow-up Question 24: These records can contain patient specific medical information that we cannot make public. Redacted copies are probably available via Freedom of Information requests.

My Follow Up Question 25. Are you keeping track? Can you please make publicly available the amount of complaints that you have received

FDA Answer to Follow-up Question 25: The FDA does keep track. We can look into making the amount of complaints publically available.

What is the timeline for response to these concerns and reports?

The agency reviews these reports within one month. We only contact the responder if further information or clarification appears to be needed.

My Follow Up Question 26. Then what do you do with the information?

What is the procedure for reporting and what reports are the FDA generating on the issue?

To report a problem that appears to be related to electronic product radiation, please see our website at: *https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ ReportaProblem/default.htm.* FDA has not generated a report on reports it has received from individuals attributing their symptoms to RF exposure from consumer communications products.

FDA Answer to Follow-Up Question 26: An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product. The reports are required from manufacturers if the regulatory definition and criteria for requiring a report are met. Reports can come from consumers or occupational product user. The FDA reviews the reports to determine if the information indicates a defect could be present in a specific product or generally in a product type. To complete that evaluation we occasionally find we need to request more information from the manufacturer, report submitter or other relevant source.is necessary. For this product area the literature indicates that RF exposure is not a plausible cause of the problem described.

My Follow Up Question 27. Can you please generate an annual report on this. It seems important.

FDA Answer to Question 27: The FDA has not generated annual reports on cell phone complaints.

11. Will the FDA be recommending that the NTP now do a systematic review of radiofrequency considering the research results? If so when? If not, please explain why not-considering the widespread proliferation of cell phones. Please see where the FDA can nominate this issue for systematic review here – The NTP Office of Health Assessment and Translation (OHAT) develops literature-based evaluations to reach conclusions about potential human health hazards and to examine the state of the science. https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html.

We have not asked NTP to perform a systematic review for several reasons, including the fact that there are already numerous high quality expert reports, formal reviews, and meta-analyses related to the safety of use of RF consumer communication products.

My Follow Up Question 28. Please list those you are referring to. As far as I know, there are no systematic reviews that have been done and the US has not looked at this for over 20 years.

FDA Answer to Follow-Up Question 28: The IEEE International Committee on Electromagnetic Safety has posted a list of statements from governments and expert panels concerning research and conclusions about the possibility of health effects and safe exposure levels of radiofrequency energy. Many of these organizations have further analysis at their own web sites. Many of these organizations go into great detail on their analysis and have extensive bibliographies. The link to the IEEE website is attached. http://www.ices-emfsafety.org/expert-reviews/
In addition, the WHO EMF Project is currently updating the relevant Environmental Health Criteria.

My Follow Up Question 29: The WHO EMF Project was started with industry funded and is lead by an engineer and the group members are also connected to ICNIRP. It is not the same as the IARC. Is the FDA going to go with the results of the WHO EMF Project Environmental Health Criteria rather than do an independent review?

FDA Answer to Follow-up Question 29: FDA has answered this concern above. We have worked closely with the US National Academy of Science and we follow the work of expert review groups like IARC, the WHO EMF project, ICNIRP and SCENIHR. All of these expert review organizations have vetting processes for their expert scientific review panels. In addition, our scientists have been following the RF science at national and international meetings as well as via Pubmed since at least the early 1990s.
Thank you for the link. FDA has no plan to nominate this issue for systematic review at the NTP Office of Health Assessment and Translation at this time.

My Follow Up Question 30: Why not? . Please I would think a systematic review is in order considering the exposure to babies and children for a lifetime.

FDA Answer to Follow-up Question 30: There is no need for NTP to do this work for the FDA. This can be done by the FDA if necessary. Also, there are already many systematic reviews available.

Additional Questions:
My Follow Up Question 31.
Children are handed wireless laptops in classrooms across the USA. Please explain why the FDA is not informing the parents that many laptops have minimum separation distance of 20cm or 8 inches that the device should be from the body to ensure FCC compliance. The FDA should be informing the public about this distance. Why aren't they.
See this http://news.arubanetworks.com/press-release/prince-georges-county-public-schools-creates-one-nations-largest-k-12-wi-fi-deployment

FDA Answer to Follow-up Question 31: The antenna in laptop computers is usually located along the top edge of monitor of the laptop. Opening the laptop to use it puts the antenna approximately 8-10 inches away from the viewer. Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 32.

What proof of safety is there that pregnant women are protected when it comes to this radiation. They are placing laptops on their bellies. Has the FDA looked at research on impacts on pregnancy? If so, please share what studies have been reviewed.

FDA Answer to Follow-Up Question 32: The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document

entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) section 3.6.4.1 Reproductive Effects is also a good place to start a review.

My Follow Up Question 33.
Send me documentation that children adequately covered by the current US guidelines. Children absorb the radiation deeper into their brain and body. Please explain why the FDA states "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."
Why does the FDA clarify that long term effects are still being researched and children are more vulnerable to this radiation? They will have more impacts as they will have a lifetime of exposure. Why doesn't the FDA state this clearly for parents?

FDA Answer to Follow-Up Question 33: Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women. The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) is also a good place to get a compilation of published reports.

My Follow Up Question 34.
The FDA has outdated information (highlighting Interphone 2010 results) on a webpage under the cellphones section entitled Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors."
https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm212273.htm
FDA Senior staff have been asked to update these webpages 4 times over the last two years *and have not done so.* Please explain why this outdated material is being left on the FDA website.

FDA Answer to Follow-up Question 34: Thank you for your review of the FDA website on this topic. Your concern regarding the information is noted. The information is still useful.

Daniel Kassiday
SME: Electronic Product Radiation Control

Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
U.S. Food and Drug Administration
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daniel.kassiday@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=560&B=564&E=&S=E.

From: theodorams@aol.com [mailto:theodorams@aol.com]
Sent: Friday, April 14, 2017 8:39 PM
To: Kassiday, Daniel F. H.; CDRH Small Manu. Assistance; O'Hara, Michael D; Jung, William; Ochs, Robert; CDRH Ombudsman
Subject: Please respond to my follow up questions on wireless radiation

Dear Dr. Kassiday,
I appreciate you answering these questions. However for several of my questions I did not see the full explanation nor documentation for your response. Can you please answer my follow up questions. As a mother and concerned citizen I am thankful to fully understand how the FDA is making these important determinations for safety when it comes to my children and this new radiation exposure.

Thank you Theodora Scarato MSW

See my follow up question in blue.

> Follow up Questions To The FDA
>
> I asked:**Will the FDA be updating it's website to include the NTP study results on radiofrequency radiation?**
> The FDA answered:Our conclusion that current radiofrequency (RF) exposure limits adequately protect the public health has not changed based on the draft National Toxicology Program (NTP) report about a portion of NTP's study.[1] We do not anticipate a website update on the NTP study before NTP publishes a final report regarding the complete study.
>
> My Follow Up Question 1. : The results on the brain and heart cancers are final. They are not a draft In addition the research showing a genotoxic effect are now being added to the report. Even if all the other findings show "no effect" this is a significant finding. Why is the FDA waiting when children and pregnant women are actively exposing themselves to this radiation unaware that they could be racking up hours of exposure.
>
> My Follow Up Question 2. Please explain how the FDA arrived at that conclusion?
> **Why is the FDA not considering the evidence showing fertility damage from wireless and cellphones? Specifically the research on impacts on sperm DNA at non thermal levels, impacts on the ovaries and the fact that the NTP study found the exposed group had offspring with lower birth weight. See research study found here in the drop down: http://ehtrust.org/science/research-on-wireless-health-effects/**
> We have looked at the papers you identified. Those studies suffer from many confounding factors that significantly limit or eliminate their impact. There is insufficient evidence available to establish adverse health effects, including when these studies are taken into account.
>
> My Follow Up Question 3. So you are stating that all these studies are insufficient. On what grounds? What do you think of this study please in particular as the majority of studies showed an effect.
> Houston B., et al. "The effects of radiofrequency electromagnetic radiation on sperm function." Reproduction, 2016.

- Among a total of 27 studies investigating the effects of RF-EMR on the male reproductive system, negative consequences of exposure were reported in 21. Within these 21 studies, 11 of the 15 that investigated sperm motility reported significant declines, 7 of 7 that measured the production of reactive oxygen species documented elevated levels and 4 of 5 studies that probed for DNA damage highlighted increased damage, due to RF-EMR exposure. Associated with this, RF-EMR treatment reduced antioxidant levels in 6 of 6 studies that studied this phenomenon, while consequences of RF-EMR were successfully ameliorated with the supplementation of antioxidants in all 3 studies that carried out these experiments.

What are the confounding factors on this study please.
Avendaño C, Mata A, Sanchez Sarmiento CA, Doncel GF.(2012). Use of laptop computers connected to internet through Wi-Fi decreases human sperm motility and increases sperm DNA fragmentation. Fertility Sterility. 97(1), 39-45.

This conclusion is consistent with recent expert reports on radiofrequency. For example, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015 concluded, "The previous SCENIHR Opinion concluded that there were no adverse effects on reproduction and development from RF fields at non-thermal exposure levels. The inclusion of more recent human and animal data does not change that assessment. Therefore, it is concluded that there is a strong overall weight of evidence against an effect of low-level RF fields on reproduction or development."[2]

My Follow Up Question 4. Is the FDA's stance to consider the SCENIHR opinion as the FDA's opinion?
My Follow Up Question 5. What review has the FDA done on fertility research. Please document and share this analysis.
Regarding your particular concern related to body weight, the NTP's draft report states, "Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation.[3]"
My Follow Up Question 6. Please see on Page 8 the following:

- RESULTS

- In pregnant rats exposed to 900 MHz GSM- or CDMA-modulated RFR, no exposure-related effects were observed on the percent of dams littering, litter size, or sex distribution of pups. Small, exposure-level-dependent reductions (up to 7%) in body weights compared to controls were observed throughout gestation and lactation in dams exposed to GSM- or CDMA- modulated RFR. In the offspring, litter weights tended to be lower (up to 9%) in GSM and CDMA RFR-exposed groups compared to controls. Early in the lactation phase, body weights of male and female pups were lower in the GSM-modulated (8%) and CDMA-modulated (15%) RFR groups at 6 W/kg compared to controls. These weight differences in the offspring for both GSM and CDMA exposures tended to lessen (6% and 10%, respectively) as lactation progressed. Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation n in all groups of male rats exposed to GSM-modulated RFR

-

The quote you sent me is not adequate to address the concern I raised. As you can see from this paragraph, the weights were lower (see my yellow highlighted areas above) after prenatal exposure. You sent me details that pertain to the animals later in the study. (My daughter was a low birth weight when she was born and has caught up now.) The fact is that an effect of lower birth weight was found at non thermal levels. This indicates an important non thermal effect. (Smoking caused babies to be smaller as well and the industry stated this was good for mothers and doctors recommended that women smoke if they were gaining to much

weight during pregnancy.) Please explain why the FDA is not considering this effect and investigating the issue. Clearly non- thermal effects are evident from this study. Please explain the FDA's analysis on the issue of these lower body weights.

3. **Is it still the FDA's position that the weight of evidence does not show health effects? If so, please provide the documentation that supports this position by the FDA in light of the NTP results. In a prior email dated February 5, 2016 Email RE-Question about the FDA and radiofrequency radiation this is what you told me. Please provide the scientific research that shows safety.**

The FDA's position has not changed. Based on the available scientific evidence, including published literature and published expert reports, the Agency has concluded that the current RF exposure limits provide adequate protection for use of RF consumer communication electronic products like cell phones.

My Follow Up Question 7. Please send me the "the available scientific evidence, including published literature and published expert reports" the FDA specifically looked at to state that "the Agency has concluded that the current RF exposure limits"

Many expert reports have been released that discuss the strengths and weaknesses of the published literature.[4],[5] There have also been formal analyses and reviews of published expert reports.[6],[7]

You cite two reviews but is this how the FDA investigates ? by citing two reviews well cited by industry funded scientists? It is notable that this review "International and national expert group evaluations: biological/health effects of radiofrequency fields." not only cites industry linked reports but the authors state: "We thank Chung-Kwang Chou (chairman, SC-95 of the international committee on electromagnetic safety, Institute of Electrical and Electronic Engineers) for critical reading of the manuscript and helpful suggestions." CKChou is former Chief Motorola Scientist.

My Follow Up Question 8. Are these reviews that you refer to from organization that the FDA then is taking on as it's own opinion? How does the FDA determine that these reviwes are scientifically sound and unduly influenced by industry?

4. **Does the FDA consider oxidative stress a health effect? I sent you a review article last year about this and it seems important to share with the American people (http://nebula.wsimg.com/107f00a88ae36803a132e3ca6c222157?AccessKeyId=045114F8E0676B9465FB&disposition=0&alloworigin=1)**

Thank you for the review article on oxidative stress. We have reviewed it, and it contains opinions that have added to our understanding of the topic.

In the World Health Organization (WHO) International Agency for Research on Cancer (IARC) monograph 102 (2013), the IARC expert working group concluded that there was only weak evidence that adverse health effects could be caused by RF due to oxidative stress. We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects.

My Follow Up Question 9. How do you substantiate such a statement ?
"We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects."

My Follow Up Question 10. Does the FDA think that oxidative stress can impact health.

the research study here states that constant oxidative stress over tome can lead to health problems. Please review and explain why this has not impacted the view of the FDA.

5. **If the FDA is supposed to protect the public then they need to inform the public of the fine print instructions the manual related to RF. Why is the FDA not acting on this and informing people of the fine print instructions on RF on cell phones and wireless devices? Children are carrying phones on their bodies, tucked in spandex pants and in bras and jeans in school classrooms. Can you please explain why the FDA is not ensuring the public is aware of the fine print warnings?**

There is a large safety factor included in the public exposure limit (see IEEE Std. C95.1-2005 Annex C, *Rationale*, for more information regarding this safety factor).

My Follow Up Question 11. What does the FDA think the safety factor is for SAR exposure limits. Please state it.

We note that Federal Communications Commission (FCC) guidance on general RF exposure procedures and equipment authorization policies for mobile and portable devices explains that for devices designed to operate in contact with the body, the specific absorption rate (SAR) compliance tests should be conducted a separation distance of 5 mm or less (FCC KDB 447498 D01 section 4.2.2).

My Follow Up Question 12. Why does the FDA not share this information with the public? Why are these separation distances not stated on the FDA website so that te American people are aware of it. I have a teenage daughter and her friends do the following: They place the cell phone in their spandex pants against their skin. They lay the phone on their lap as they watch music videos or stream and facetime. They also sleep with the phone next to their head. They easily can roll over and sleep on the cell phone. Women carry cell phones in their bra all the time. The public is unaware. Again- Why does the FDA not share this information with the public on their website? So far it is a secret.

Additionally, that FCC guidance explains that mobile and portable devices designed to be used with a body-worn accessory must be tested for body-worn accessory SAR compliance. According to the guidance, a conservative minimum test separation distance should be used for such testing, at worst case using no more than a 25 mm separation distance. The same FCC guidance states that operating manuals must include specific information to allow users to select body-worn accessories that meet the compliance test separation distance requirements, and all supported body-worn accessory operating configurations must be clearly disclosed to users, through conspicuous instructions in the user guide and user manual, to ensure unsupported operations are avoided.

My Follow Up Question 13. Everyone I have spoken to to is 100% unaware of this information buried in manuals. Please explain how the FDA has decided it is not their responsibility to inform the public on this. Has the FDA done a survey?

Additionally, cell phone RF exposure compliance testing must be determined at the maximum average power level.

My Follow Up Question 14. Well actually you will use your cell phone at maximum power under several conditions such as if you are far from a tower with lower bars- or in an elevator, in a moving car far from a tower and video streaming- as you are aware. So it is possible. Is the FDA saying that although it is possible to be at maximum power, it is not necessary for the public to be aware because it does not happen often? There are many moments when people use phones in maximum power conditions- especially when they have a lot of applications on at once far from a base station. Please explain why the FDA is rationalizing not telling people about this.

In order to conserve battery life, cell phones seldom actually operate at maximum power, which reduces the SAR proportionately.

My Follow Up Question 15. Can you tell me what data you have on how "cell phones seldom actually operate at maximum power" How often do they opeate at maximum power.

6. I understand that the RFIAWG was given a presentation of these findings. What is the FDA perspective on the findings now that you have reviewed them please? Please detail the next steps for the FDA with a timeline.

The U.S. Radiofrequency Interagency Working Group (RFIAWG) has not had a presentation on findings from the NTP study.

My Follow Up Question 16. Why hasn't the U.S. Radiofrequency Interagency Working Group (RFIAWG) had a presentation on these findings? I thought the Groups role was to provide some sort of oversight? Why are they not given a full presentation?

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My Follow Up Question 18. How did you determine that conclusion? What is the rationale for FDA's conclusions?

When NTP completes its analysis and a full report is available, we will review it and consider what, if any, effect it has on the agency's thinking regarding risks associated with RF exposure from cell phones.

My Follow Up Question 19. Can you please explain the review process for the FDA and the transparency that will be involved in the review.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue. What questions are being asked and of whom? What other FDA staff are involved in the process. Are any consultants working with the FDA? Who are they?

The Center for Devices and Radiological Health (CDRH) is the FDA center that regulates electronic products under the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act. Note: EPRC may also be referred to as "Radiological Health." Questions or concerns can be sent to the FDA document mail center:

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue
WO66-5521
Silver Spring, MD 20993-0002

Marking the documents, "Attn: Division of Radiological Health" can help expedite routing to the Division of Radiological Health for review and appropriate follow-up. The staff in other divisions and offices who have the required expertise to answer specific questions are called upon for assistance when a need occurs. If necessary, we could call on expertise from other government (international, national, state, etc.) agencies, concerned consumer groups, or industry.

My Follow Up Question 20. You did not answer my questions so here they are again.
Who is the point person at the FDA for this issue and what are they doing in regards to this issue?

What questions are being asked and of whom?
What other FDA staff are involved in the process.
Are any consultants working with the FDA? If so- Who are they?

8. **The NTP study found DNA damage in the brain; please detail the FDA response to these findings and the next steps in terms of protecting the people.**
We assume your question is referring to the draft supplemental NTP document that covers experiments looking for DNA damage. Our conclusion that current RF exposure limits adequately protect the public health has not changed based on our review of the draft NTP supplemental papers.

The NTP comet assay, indicated DNA damage (see the table).

MALE						
Rats	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
Mice	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
FEMALE						
Rats	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
Mice	CDMA	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	GSM	Frontal cortex	Cerebellum	Hippocampus	Liver	Blood
	statistically significant trend and pairwise SAR-dependent increase					
	statistically significant trend or pairwise increase					
	no significantly different but increase in two or more groups					

My Follow Up Question 21. Please explain how this DNA damage found in the comet assay - not change the FDA opinion?
My Follow Up Question 22. What would change the FDA opinion? How much evidence is necessary?

9. **Is the FDA preparing a response to inform the FCC of the official recommendations to the issue of cell phones and wireless? Please give specifics on the timelines.**
As a general policy, the FDA does not comment on pending matters that are under review. If FDA had concerns regarding the current RF exposure limits, the agency would communicate those concerns to FCC.

My Follow Up Question 23. I thought that a transparent process was underway and that all comments would be available. The FCC states they are looking to their federal partners for guidance as they are not a health and safety agency. If the FDA does not give any comments then I wonder who will. Will the FDA be commenting at all to the FCC in their Proceeding Number 13-84? Have they ever commented?

10. **The FDA has received reports of people who develop headaches, nerve damage and rashes from cell phone and wireless use. What is being done by the FDA to monitor these side effects?**
The FDA has received anecdotal reports from individuals that attribute their symptoms to RF exposure from cordless phones and cell phones. The anecdotal reports are reviewed to determine if they contain new information indicating that RF radiation from an electronic product caused the adverse health effects described. No such evidence has been revealed through our review of those reports. We also monitor literature regarding experiments intended to prove or disprove a causal link between RF exposure and adverse health effects as well as literature regarding the most effective treatments for individuals suffering from these symptoms.

Where can these reports be accessed online?
Currently, these reports cannot be publicly accessed online.
My Follow Up Question 24. Why not, Can you please make them available.
My Follow Up Question 25. Are you keeping track? Can you please make publicly available the amount of complaints that you have received

What is the timeline for response to these concerns and reports?
The agency reviews these reports within one month. We only contact the responder if further information or clarification appears to be needed.

My Follow Up Question 26. Then what do you do with the information?
What is the procedure for reporting and what reports are the FDA generating on the issue?
To report a problem that appears to be related to electronic product radiation, please see our website at: *https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ ReportaProblem/default.htm.* FDA has not generated a report on reports it has received from individuals attributing their symptoms to RF exposure from consumer communications products.

My Follow Up Question 27. Can you please generate an annual report on this. It seems important.

11. **Will the FDA be recommending that the NTP now do a systematic review of radiofrequency considering the research results? If so when? If not, please explain why not-considering the widespread proliferation of cell phones. Please see where the FDA can nominate this issue for systematic review here – The NTP Office of Health Assessment and Translation (OHAT) develops literature-based evaluations to reach conclusions about potential human health hazards and to examine the state of the science. https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html.**
We have not asked NTP to perform a systematic review for several reasons, including the fact that there are already numerous high quality expert reports, formal reviews, and meta-analyses related to the safety of use of RF consumer communication products.

My Follow Up Question 28. Please list those you are referring to. As far as I know, there are no systematic reviews that have been done and the US has not looked at this for over 20 years.

In addition, the WHO EMF Project is currently updating the relevant Environmental Health Criteria.

My Follow Up Question 29: The WHO EMF Project was started with industry funded and is lead by an engineer and the group members are also connected to ICNIRP. It is not the same as the IARC. Is the FDA going to go with the results of the WHO EMF Project Environmental Health Criteria rather than do an independant review?

Thank you for the link. FDA has no plan to nominate this issue for systematic review at the NTP Office of Health Assessment and Translation at this time.

My Follow Up Question 30: Why not? . Please I would think a systematic review is in order considering the exposure to babies and children for a lifetime.

Additional Questions:

My Follow Up Question 31.
Children are handed wireless laptops in classrooms across the USA. Please explain why the FDA is not informing the parents that many laptops have minimum separation distance of 20cm or 8 inches that the device should be from the body to ensure FCC compliance. The FDA should be informing the public about this distance. Why aren't they.

See this http://news.arubanetworks.com/press-release/prince-georges-county-public-schools-creates-one-nations-largest-k-12-wi-fi-deployment

My Follow Up Question 32.
What proof of safety is there that pregnant women are protected when it comes to this radiation. They are placing laptops on their bellies. Has the FDA looked at research on impacts on pregnancy? If so, please share what studies have been reviewed.

My Follow Up Question 33.
Send me documentation that children adequately covered by the current US guidelines. Children absorb the radiation deeper into their brain and body. Please explain why the FDA states "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."

Why does the FDa clarify that long term effects are still being researched and children are more vulnerable to this radiation? They will have more impacts as they will have a lifetime of exposure. Why doesn't the FDA state this clearly for parents?

My Follow Up Question 34.
The FDA has outdated information (highlighting Interphone 2010 results) on a webpage under the cellphones section entitled Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors."
https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm212273.htm

FDA Senior staff have been asked to update these webpages 4 times over the last two years *and have not done so.* Please explain why this outdated material is being left on the FDA website.

Gmail Theodora Scarato <theodora.scarato@ehtrust.org>

Urgent: Unanswered Questions About Transparency at WHO from Scientists RE Radiation

1 message

Theodora Scarato <Theodora.Scarato@ehtrust.org> Tue, Oct 6, 2020 at 8:22 AM
To: vandeventere@who.int, emfproject@who.int, postmaster@euro.who.int, bustreof@who.int, neiram@who.int
Cc: CarrZ@who.int, perenzinp@who.in, zastenskayai@who.int, onyonl@who.int, kimr@who.int, cakong@who.int, jimenezp@paho.org, vergerp@who.int, Maria.Marinissen@hhs.gov

Dear Dr. Van Deventer,

I was writing as we have not recieved an answer to these questions send in November (and previously in January 2019). Could you please respond to these questions regardng the WHO EMF Project?
Also, Please see attached research studies. I will add a question- Please clarify if WHO has investigated the effects of Radiofrequency to trees, birds, insects and wildlife. If not, who is monitoring this? Please clarify on WHO EMF project webpages that the effects to the environment are not considered.

In addition, when will the findings of "clear evidence of cancer" and DNA damage from the National Toxicology Program Study on Cell Phone Radiation be added to the website?
Thank you very much,
Theodora Scarato

In addition, I have been informed by experts that they are a participating country in the WHO EMf Project but did not participate in the writing of the latest factsheet on 5G, nor on any factsheets found on the WHO EMF Project website so please clarify how such content is being drafted and reviewed in detail. Thank you so much,

---------- Forwarded message ---------
From: **Theodora Scarato** <Theodora.Scarato@ehtrust.org>
Date: Wed, Nov 27, 2019 at 11:06 AM
Subject: Fwd: Question by scientists regarding transparency of WHO EMF Project
To: <vandeventere@who.int>

Dear Dr. Vandeventer,
This is updated with new signatories. More to come.

Dear Dr. Van Deventer,

This letter is in regards to the "Call for Expressions of Interest for Systematic Reviews (2019)."

1. Who specifically will select the teams?
2. What are the criteria of selection?
3. One issue often missed in CIO forms are financial relationships between universities and companies. For example, New York University Wireless is so heavily funded by telecommunications companies that it was stated that "the affiliates share in it like an

R&D arm." Will industry funding of universities be stated on the COI forms?

4. The WHO EMF Project has several factsheets online. Which scientists wrote these and what was the process for the conclusions put forth in these factsheets?
   - 5G mobile networks and health
   - Electromagnetic fields and public health: mobile phones Revised October 2014
     Q&As on mobile phones and their base stations 2013
     Exposure to extremely low frequency fields - Backgrounder (June 2007)
     Base stations and wireless networks - Backgrounder (May 2006)
     Electromagnetic hypersensitivity - Backgrounder December 2005
     Static electric and magnetic fields - Backgrounder (March 2006)

5. Will scientists who are also a part of ICNIRP be identified in the COI process?
   Question added by Theodora Scarato 6. Please clarify if WHO has investigated the effects of Radiofrequency to trees, birds, insects and wildlife. If not, who is monitoring this? Please clarify on WHO EMF project webpages that the effects to the environment are not considered.

Signed
Henry Lai, PhD, Professor Emeritus, University of Washington, Seattle, WA

Simona Carrubba, PhD, Mercyhurst University, Erie, PA

Kjell Hansson Mild
Department of Radiation Sciences Umeå University SE-901 87 Umeå, Sweden

Semra Tepe Çam, Assoc.Prof.
Turkish Atomic Energy Authority Ankara Turkey

Alvaro Augusto de Salles, Ph.D.
Professor, Federal University of Rio Grande do Sul- UFRGS, Porto Alegre, Brazil

Alfonso Balmori, BSc
Biologist. Spain

Samuel Milham MD, MPH.
Retired Washington State Health Department

Kavindra Kesari, Ph.D,
Senior Scientist, Department of Applied Physics, Aalto University, Espoo, Finland

Livio Giuliani,
"dirigente di ricerca" of Italian National Health Service, ICEMS Spokesman

Jerry L. Phillips, Ph.D.
Executive Director, Excel Centers, Professor Attendant, Department of Chemistry & Biochemistry

David O. Carpenter, M.D.

Director, Institute for Health and the Environment, University at Albany

Wenjun Sun, PhD
Professor, Zhejiang University School of Medicine, Hangzhou, China

Lukas H. Margaritis
Professor Emeritus of Cell Biology and Radiobiology, Dept of Cell Biology and Biophysics Faculty of Biology, University of Athens

Carl F. Blackman
U.S. Environmental Protection Agency (1970-2014), Retired

Dr. Besarion Partsvania
Georgian Technical University

Hidetake Miyata, PhD.,
Associate Professor, Department of Physics, Tohoku University, Japan

Marie-Claire Cammaerts,
University of Brussels, Belgium, Retired

Martin L. Pall PHD
Professor Emeritus of Biochemistry and Basic Medical Sciences, Washington State University

Theodora Scarato
Executive Director
Environmental Health Trust
EHTrust.org

Our Mission
To safeguard human health and the environment by empowering people with state-of-the-art information.

6 attachments

2019 Belyaev Regularities Health Risks Non-Thermal Microwaves of Mobile Communication.pdf
227K

adverse-health-effects-of-5g-mobile-networking-technology-under-real-life-conditions.pdf
674K

Radiofrequency radiation injures trees around mobile phone base stations copy.pdf
674K

Carpenter Bandara Planetary electromagnetic pollution- it is time to assess its impact copy 2.pdf
383K

Exposure of Insects to RadioFrequency Electromagnetic Fields from 2 to 120GHz 5g copy.pdf
1695K

Miller et al (1). Cancer epidemiology update copy.pdf
233K

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ENVIRONMENTAL HEALTH TRUST

For U.S. Mail
P.O. Box 58
Teton Village WY 83025
www.ehtrust.org

Re: Environmental and Health Effects of Telecommunications Infrastructure

Dear Federal Communications Commission

Environmental Health Trust (EHT) is a nonprofit think tank and policy organization, founded in 2007, dedicated to identifying and reducing environmental health hazards. EHT provides independent scientific research and advice on controllable environmental hazards to local, state, and national governments. Today, we write to advise you of the published scientific grounds establishing why and how to avoid major health and environmental impacts from the installation of 5G wireless telecommunications facilities and associated wireless infrastructure in neighborhoods, parks and wilderness.

For 5G to operate for the foreseeable future, this will need to rely on 3G, 4G, and 5G technologies in order to allow existing devices to communicate. At this point, most 3G and 4G towers are located far from densely populated areas, for example at specified heights of tens of meters. A number of the proposed placements of 5G require close proximity to human habitation because the 5G signals cannot penetrate solid structures and are required every hundred meters or less. The transmissions to and from these proposed microwave wireless installations are emissions that are an environmental pollutant known to cause cancer (in both experimental animals and humans), DNA damage, neurological damage and other adverse health and environmental effects (e.g., on birds, bees, and trees) according to internationally recognized authoritative research. The prestigious institutions that have conducted these studies include the U.S. National Toxicology Program, the nation's premier testing institute, and the Ramazzini Institute, a foremost testing center of Italy.

The current guidelines put forth by the self-appointed, self-monitored, minority viewpoint of the International Commission on Non-Ionizing Radiation Protection (ICNIRP), upon which European standards are based are not protective to humans as they are not based on documentation of safety for long term exposure. Furthermore, none of the limits was developed to ensure safety to flora and fauna. As the Natural Resources Defense Council has argued in U.S Courts, an environmental impact assessment should be performed before building out these networks.

Below we explain why more than 400 expert scientists and numerous medical professionals are calling for a halt to 5G and for the immediate reductions in both public exposure to microwave wireless radiation and the densification of wireless infrastructure[12].

ICNIRP and FCC Limits Do not Protect People, Wildlife or the Environment

The exposure guidelines developed by the FCC and ICNIRP, were principally designed to protect against adverse thermal effects *only* and were based on studies of short-term high intensity exposures to animals. FCC and ICNIRP limits were not set after adequate investigations into effects after long term chronic exposure- the type of exposure the public will receive from 5G/4G densification. Research on impacts to the developing brain of children was not factored into the standard setting decisions of these groups decades ago, nor do these groups consider adverse impacts on male and female reproduction or DNA damage that has been shown to occur as a result of chronic non-thermal exposures.

The following is a sampling of counties with cell tower network radiofrequency radiation (RF) limits (maximum permissible limits) below ICNIRP and FCC limits: Belarus, Bulgaria, China, Lithuania, Poland, Russia, Belgium, Chile, Greece, India, Israel, Italy, Liechtenstein and Switzerland[34567].

Countries such as India, China and Russia have much lower limits than ICNIRP and are considered "science based[8]." These limits are more stringent because they take into account research indicating adverse nonthermal health effects. According to Russian radiation experts, the following health hazards are likely to be faced in the near future by children who regularly use mobile phones: disruption of memory, decline in attention, diminished learning and cognitive abilities, increased irritability, sleep problems, increase in sensitivity to stress, and increased epileptic readiness. For these reasons, special recommendations on child safety from mobile phones have been incorporated into the current Russian mobile phone standard."[9] China's cell tower limits are based on science showing effects which include behavioral, neurological, reproductive abnormalities, and DNA damage[10]. In 2011 the Parliamentary Assembly of the Council of Europe issued Resolution 1815: "The Potential Dangers of Electromagnetic

[1] "Small Cell Towers, Mini Cell Towers, Wireless Facilities and Health: Letters from Scientists on the Health Risk of 5G," Environmental Health Trust, last modified September 20, 2017, https://ehtrust.org/small-cells-mini-cell-towers-health-letters-scientists-health-risk-5g/.
[2] The signatories – 5G Appeal 5G Appeal
[3] https://apps.who.int/gho/data/node.main.EMFLIMITSPUBLICRADIOFREQUENCY?lang=en
[4] Wu T, Rappaport TS, Collins CM. Safe for Generations to Come. *IEEE Microw Mag*. 2015;16(2):65-84. doi:10.1109/MMM.2014.2377587
[5] China Rationale for Setting EMF Exposure Standards* Prof. Dr. Huai Chiang as referenced by Wu 2015
[6] Comparison of international policies on electromagnetic fields (power frequency and radiofrequency fields), Rianne Stam, National Institute for Public Health and the Environment
[7] Mary Redmayne (2016) International policy and advisory response regarding children's exposure to radio frequency electromagnetic fields (RF-EMF)Electromagnetic Biology and Medicine, 35:2, 176-185, DOI: 10.3109/15368378.2015.1038832
[8] Wu T, Rappaport TS, Collins CM. Safe for Generations to Come. *IEEE Microw Mag*. 2015;16(2):65-84. doi:10.1109/MMM.2014.2377587
[9] Scientific basis for the Soviet and Russian radiofrequency standards for the general public

[10] Prof. Dr. Huai Chiang. Rationale for Setting EMF Exposure Standards. Accessed July 8, 2020.

Fields and Their Effect on the Environment.[11][12]" A call to European governments to "take all reasonable measures" to reduce exposure to electromagnetic fields "particularly the exposure to children and young people who seem to be most at risk from head tumours." Resolution 1815 specifically states that governments "reconsider the scientific basis for the present standards on exposure to electromagnetic fields set by the International Commission on Non-Ionising Radiation Protection, which have serious limitations, and apply ALARA principles, covering both thermal effects and the athermic or biological effects of electromagnetic emissions or radiation."

In 2012, t India's National Ministry of the Environment and Forest issued a report on the potential impacts of communication towers on wildlife with a focus on birds and bees, citing hundreds of research studies that found adverse effects. Recommendations from the Ministry include, "Introduce a law for protection of urban flora and fauna from emerging threats like ERM/EMF as conservation issues in urban areas are different from forested or wildlife habitats."[13] This research was published in the journal Biology and Medicine concluding "that out of the 919 research papers collected on birds, bees, plants, other animals, and humans, 593 showed impacts, 180 showed no impacts, and 196 were inconclusive studies." As a result of this research, the government tightened their allowable levels of radiofrequency radiation to 1/10 th of ICNIRP limits[14].

As part of this letter, we are also submitting to you the July 8, 2020 letter to EHT Director Theodora Scarato from the Environmental Protection Agency's Director of the Radiation Protection Division and Office of Radiation and Indoor Air, Lee Ann B. Veal, that confirms that the EPA has never reviewed the impact of microwave radiation on birds, bees, or trees. Nor has any U.S. federal health agency ever set safety limits for trees, birds, or bees or the physical environment. No agency has a funded mandate to ensure our flora and fauna are safe from cell tower radiation. In other words, it is a gaping hole in federal accountability. The U.S. Department of the Interior sent a letter in 2014[15] reviewing several research studies showing harm to birds and concluding that "The electromagnetic radiation standards used by the Federal Communications Commission (FCC) continue to be based on thermal heating, a criterion now nearly 30 years out of date and inapplicable today."

A now-retired U.S. Fish and Wildlife Service wildlife biologist, the former lead on telecommunications impacts, Dr. Albert Manville, has written to the FCC on impacts to birds and on higher frequencies to be

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[11] Committee on the Environment, Agriculture and Local and Regional Affairs, Resolution 1815: "The Potential Dangers of Electromagnetic Fields and Their Effect on the Environment," Doc. 12608, May 6, 2011, https://pace.coe.int/en/files/13137/html.

[12] Parliamentary Assembly of the Council of Europe, Resolution 1815 Final Version, May 27, 2011, http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=17994&.

[13] Expert Committee, Ministry of Environment and Forest, Government of India, Report on Possible Impacts of Communication Towers on Wildlife Including Birds and Bees, Constituted on 30th August, 2010.

[14] S. Sivani and D. Sudarsanam, "Impacts of Radio-Frequency Electromagnetic Field (RF-EMF) from Cell Phone Towers and Wireless Devices on Biosystem and Ecosystem – A Review," *Biology and Medicine* 4, no.4 (January 2013), https://www.biolmedonline.com/Articles/Vol4_4_2012/Vol4_4_202-216_BM-8.pdf.

[15] Washington DC, Veenendaal ME. Department of Interior Letter. *United States Department of the Interior OFFICE OF THE SECRETARY.*

used in 5G. Dr. Manville authored numerous publications detailing research showing harm to birds.[16,17,18] "The race to implement 5G and the push by FCC to approve the related 5G license frequencies to industry are very troubling and downright dangerous."

Scientists have not developed a safety standard that stipulates a "safe level."

Documented Impacts to Wildlife and the Environment

- "A review of the ecological effects of RF-EMF" reviewed 113 studies finding RF-EMF had a significant effect on birds, insects, other vertebrates, other organisms, and plants in 70% of the studies (Cucurachi 2013). Development and reproduction in birds and insects were the most strongly affected. As an example of the several studies on wildlife impacts, a study focusing on RF from antennas found increased sperm abnormalities in mice exposed to RF from GSM antennas (Otitoloju 2010).
- "Exposure of Insects to Radio-Frequency Electromagnetic Fields from 2 to 120 GHz" published in Scientific Reports is the first study to investigate how insects (including the Western honeybee) absorb the higher frequencies (2 GHz to 120 GHz) to be used in the 4G/5G rollout. The scientific simulations showed increases in absorbed power between 3% to 370% when the insects were exposed to the frequencies. Researchers concluded, "This could lead to changes in insect behaviour, physiology, and morphology over time…."
- Studies on bees have found behavioral effects (Kumar 2011, Favre 2011), disrupted navigation (Goldsworthy 2009, Sainudeen 2011, Kimmel et al. 2007), decreasing egg laying rate (Sharma and Kumar, 2010), and reduced colony strength (Sharma and Kumar, 2010, Harst et al. 2006).
- Research has also found a high level of damage to trees from antenna radiation. For example, a field monitoring study spanning 9 years involving over 100 trees (Waldmann-Selsam 2016) found trees sustained more damage on the side of the tree facing the antenna.
- A study on Aspen trees near Lyons, Colorado entitled "Adverse Influence of Radio Frequency Background on Trembling Aspen Seedlings" published in the *International Journal of Forestry* found adverse effects on growth rate and fall anthocyanin production, concluding that "results of this preliminary experiment indicate that the RF background may be adversely affecting leaf and shoot growth and inhibiting fall production of anthocyanins associated with leaf senescence in Trembling Aspen seedlings. These effects suggest that exposure to the RF background may be an underlying factor in the recent rapid decline of Aspen populations. Further studies are underway to test this hypothesis in a more rigorous way."[19]
- An analysis of 45 peer-reviewed scientific publications (1996–2016) on changes in plants due to the non-thermal RF-EMF effects from mobile phone radiation entitled "Weak radiofrequency radiation exposure from mobile phone radiation on plants" concludes, "Our analysis demonstrates that the data from a substantial amount of the studies on RF-EMFs from mobile phones show

[16] ECFS Filing Detail. https://www.fcc.gov/ecfs/filing/10603156011 99. Accessed July 8, 2020.
[17] Albert M. Manville Ph.D. Former U.S. Fish and Wildlife Service Senior Biologist. Memorandum on the Bird and Wildlife Impacts of Non-ionizing Radiation. Environmental Health Trust. Accessed July 8, 2020.
[18] Manville AM. *Collisions, Electrocutions, and Next Steps-Manville BIRD STRIKES AND ELECTROCUTIONS AT POWER LINES, COMMUNICATION TOWERS, AND WIND TURBINES: STATE OF THE ART AND STATE OF THE SCIENCE B NEXT STEPS TOWARD MITIGATION 1*.; 2002.
[19] Katie Haggerty, "Adverse Influence of Radio Frequency Background on Trembling Aspen Seedlings: Preliminary Observations," *International Journal of Forestry Research*, vol. 2010, Article ID 836278, 7 pages, 2010. doi.org/10.1155/2010/836278.

physiological and/or morphological effects (89.9%, $p < 0.001$). Additionally, our analysis of the results from these reported studies demonstrates that the maize, roselle, pea, fenugreek, duckweeds, tomato, onions and mungbean plants seem to be very sensitive to RF-EMFs. Our findings also suggest that plants seem to be more responsive to certain frequencies…."[20]

Electromagnetic Fields Alter Animal and Insect Orientation

Science of the Total Environment published environmental scientist Alforso Balmori's "Anthropogenic radiofrequency electromagnetic fields as an emerging threat to wildlife orientation," which states, "Current evidence indicates that exposure at levels that are found in the environment (in urban areas and near base stations) may particularly alter the receptor organs to orient in the magnetic field of the earth. These results could have important implications for migratory birds and insects, especially in urban areas, but could also apply to birds and insects in natural and protected areas where there are powerful base station emitters of radio frequencies. Therefore, more research on the effects of electromagnetic radiation in nature is needed to investigate this emerging threat."[21]

Multiple research studies have documented how animals' magnetoreception can be disrupted by external electromagnetic fields, from mice[22] to cows to dogs to birds.[23] Electromagnetic exposure is especially disruptive to migratory birds.[24] Electromagnetic fields have been shown to disrupt the magnetic compass orientation used by birds to navigate.[25,26] Researchers have suggested this disruption of magnetoreception is due to cryptochrome photoreceptors that allow birds to use built-in receptors as a biological compass.

A 2017 report to UNESCO[27] by botanist Mark Broomhall details the association between increasing amounts of electromagnetic radiation from cellular antennas on the Mt. Nardi tower complex and species disappearance and exodus from the Mt. Nardi area of the Nightcap National Park World Heritage Area during a 15-year period (2000–2015). He estimates "in both volume and species that from 70 to 90% of the wildlife has become rare or has disappeared from the Nightcap National Park within a radius of the Mt. Nardi tower complex. This statement can be summarised with concrete data: 3 bat species once common have become rare or gone, 11 threatened and endangered bird species are gone, 11 migratory

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[20] Malka N. Halgamuge (2017) Review: Weak radiofrequency radiation exposure from mobile phone radiation on plants, *Electromagnetic Biology and Medicine*, 36:2, 213-235, DOI: 10.1080/15368378.2016.1220389.
[21] Alfonso Balmori, Anthropogenic radiofrequency electromagnetic fields as an emerging threat to wildlife orientation, *Science of The Total Environment*, Volumes 518–519, 2015, Pages 58-60, ISSN 0048-9697, doi.org/10.1016/j.scitotenv.2015.02.077.
[22] Malkemper, E.P., et al. "Magnetoreception in the wood mouse (Apodemus sylvaticus): influence of weak frequency-modulated radio frequency fields." *Scientific Reports*, vol. 4, no. 9917, 2015.
[23] Wiltschko Roswitha, Thalau Peter, Gehring Dennis, Nießner Christine, Ritz Thorsten, Wiltschko Wolfgang. Magnetoreception in birds: the effect of radio-frequency fields.12. *Journal of The Royal Society Interface*.
[24] Engels, Svenja, et al. "Anthropogenic electromagnetic noise disrupts magnetic compass orientation in a migratory bird." *Nature* 509.7500 (2014): 353-356.
[25] Wiltschko, Roswitha, et al. "Magnetoreception in birds: the effect of radio-frequency fields." *Journal of The Royal Society Interface* 12.103 (2015): 20141103.
[26] Schwarze, S., et al. "Weak Broadband Electromagnetic Fields are More Disruptive to Magnetic Compass Orientation in a Night-Migratory Songbird (Erithacus rubecula) than Strong Narrow-Band Fields." *Front Behav Neurosci*. 10.55 (2016).
[27] Broomhall, Mark. "Report detailing the exodus of species from the Mt. Nardi area of the Nightcap National Park World Heritage Area during a 15-year period (2000-2015.)" United Nations Scientific and Cultural Organization (2017).

bird species are gone, 86 bird species are demonstrating unnatural behaviours, 66 once common bird species are now rare or gone." The Report concludes, "With these short explanations of events we can appreciate that the effects of this technology and its application on Mt. Nardi over the last fifteen years, affect not only the top of the life chain species but they are devastating the fabric of the continuity of the World Heritage, causing genetic deterioration in an insidious, massive and ever escalating scale. To truly understand what these studies reveal is to stare into the abyss."

It is very important that in considering antenna placement, there be a full environmental assessment on migratory animal patterns (from the smallest to the largest) and not simply on birds and mammals like the pronghorn but also on impacts to amphibians and insects. In addition, studies also indicate that low levels of radiation can impair processes critical to the growth and development of plants, trees, (reference Malka Halgamuge and me, 2020)

Wireless Radiation is a Public Health Issue

Human health effects include impaired reproduction, increased incidence of brain cancer, DNA breaks, oxidative stress, immune dysfunction, altered brain development, sleep changes, hyperactivity, and memory and cognitive problems.[28] Since the WHO/IARC classified EMF as a Group 2B Possible Carcinogen in 2011, the peer-reviewed research connecting wireless exposure to cancer has significantly strengthened and several scientists have published documentation that the weight of current peer-reviewed evidence supports the conclusion that radiofrequency radiation should be regarded as a human carcinogen.[29,30,31]

- The 10-year $30 million National Institute of Environmental Health Sciences National Toxicology Program's (NTP) "Studies of the Toxicology and Carcinogenicity of Cell Phone Radiation"[32,33] found that RFR was associated with "clear evidence" of cancer due to the increased malignant schwannomas found in RFR-exposed male rats. The brain (glioma) cancers and tumors in the adrenal glands were also considered evidence of an association with cancer. In addition, exposed animals had significantly more DNA damage, heart damage, and low birth weight.

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[28] For more information on acute health symptoms, see, e.g., Martin Pall, Microwave Frequency Electromagnetic Fields (EMFs) Produce Widespread Neuropsychiatric Effects Including Depression, 75 *J. Chemical Neuroanatomy* 43-51 (Sept. 2016); Response of residents living in the vicinity of a cellular phone base station in France ; Electromagnetic Fields: A Hazard to Your Health?, Healthy Children.

[29] Adams, Jessica A., et al. "Effect of mobile telephones on sperm quality: a systematic review and meta-analysis." *Environment International,* 70, 2014, pp. 106-112.

[30] Deshmukh, P.S., et al. "Cognitive impairment and neurogenotoxic effects in rats exposed to low-intensity microwave radiation." *International Journal of Toxicology*, vol. 34, no. 3, 2015, pp. 284-90.

[31] Aldad, T.S., et al. "Fetal Radiofrequency Radiation Exposure From 800-1900 MHz-Rated Cellular Telephones Affects Neurodevelopment and Behavior in Mice." *Scientific Reports,* vol. 2, no. 312, 2012.

[32] National Toxicology Program, Cell Phone Radio Frequency Radiation

[33] High exposure to radio frequency radiation associated with cancer in male rats

- The Ramazzini Institute published its findings[34] that animals exposed to very low-level RFR developed the same types of cancers as reported by the NTP.
- Long-term research on humans who have used cell phones has found increased tumors—schwannomas and glioblastomas—the same cell type as found in the NTP and Ramazzini Institute studies. Persons who started using cell phones under age 20 had the highest risk.[35]
- A 2015 Jacobs University study (replicating a 2010 study) found that weak cell phone signals significantly promote the growth of tumors in mice and that combining a toxic chemical exposure with RF more than doubled the tumor response.[36,37]
- A study published in Electromagnetic Biology and Medicine, "Impact of radiofrequency radiation on DNA damage and antioxidants in peripheral blood lymphocytes of humans residing in the vicinity of mobile phone base station," compared people living close and far from cell antennas and found that people living closer to cell antennas had higher radiation levels in the homes and several significant changes in their blood predictive of cancer development."[38]
- A 2019 study of students in schools near cell towers found their higher RF exposure was associated with impacts on motor skills, memory, and attention (Meo 2019).[39] Examples of other effects linked to cell towers in research studies include neuropsychiatric problems,[40] elevated diabetes,[41] headaches,[42] sleep problems,[43] and genetic damage.[44] Such research continues to accumulate after the 2010 landmark review study on 56 studies that reported biological effects

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[34] L. Falcioni, L. Bua, E. Tibaldi, M. Lauriola, L. De Angelis, F. Gnudi, D. Mandrioli, M. Manservigi, F. Manservisi, I. Manzoli, I. Menghetti, R. Montella, S. Panzacchi, D. Sgargi, V. Strollo, A. Vornoli, F. Belpoggi, Report of final results regarding brain and heart tumors in Sprague-Dawley rats exposed from prenatal life until natural death to mobile phone radiofrequency field representative of a 1.8 GHz GSM base station environmental emission, *Environmental Research*, Volume 165, 2018, Pages 496-503, ISSN 0013-9351, doi.org/10.1016/j.envres.2018.01.037.

[35] https://www.pathophysiologyjournal.com/article/S0928-4680(14)00064-9/fulltext

[36] Lerchl, Alexander, et al. "Tumor promotion by exposure to radiofrequency electromagnetic fields below exposure limits for humans." *Biochemical and Biophysical Research Communications,* vol. 459, no. 4, 2015, pp. 585-90.

[37] Tillmann, Thomas, et al. "Indication of cocarcinogenic potential of chronic UMTS-modulated radiofrequency exposure in an ethylnitrosourea mouse model." *International Journal of Radiation Biology,* vol. 86, no. 7, 2010, pp. 529-41.

[38]Zothansiama & Zosangzuali, Mary & Lalramdinpuii, Miriam & Jagetia, Ganesh & Siama, Zothan. (2017). Impact of radiofrequency radiation on DNA damage and antioxidants in peripheral blood lymphocytes of humans residing in the vicinity of mobile phone base stations. Electromagnetic Biology and Medicine. 36. 1-11. 10.1080/15368378.2017.1350584.

[39] Meo, S. A., Almahmoud, M., Alsultan, Q., Alotaibi, N., Alnajashi, I., & Hajjar, W. M. (2019). Mobile Phone Base Station Tower Settings Adjacent to School Buildings: Impact on Students' Cognitive Health. *American Journal of Men's Health*. doi.org/10.1177/1557988318816914.

[40] G. Abdel-Rassoul, O. Abou El-Fateh, M. Abou Salem, A. Michael, F. Farahat, M. El-Batanouny, E. Salem, Neurobehavioral effects among inhabitants around mobile phone base stations, NeuroToxicology, Volume 28, Issue 2, 2007, Pages 434-440, ISSN 0161-813X, doi.org/10.1016/j.neuro.2006.07.012.

[41] SA, Meo & Alsubaie, Yazeed & Almubarak, Zaid & Almutawa, Hisham & AlQasem, Yazeed & Hasanato, Rana. (2015). Association of Exposure to Radio-Frequency Electromagnetic Field Radiation (RF-EMFR) Generated by Mobile Phone Base Stations with Glycated Hemoglobin (HbA1c) and Risk of Type 2 Diabetes Mellitus. International Journal of Environmental Research and Public Health. 12. 14519-14528;. 10.3390/ijerph121114519.

[42] Hutter, H. P., Moshammer, H., Wallner, P., & Kundi, M. (2006). Subjective symptoms, sleeping problems, and cognitive performance in subjects living near mobile phone base stations. *Occupational and environmental medicine*, *63*(5), 307–313. doi:10.1136/oem.2005.020784.

[43] R. Santini, P. Santini, J.M. Danze, P. Le Ruz, M. Seigne, Enquête sur la santé de riverains de stations relais de téléphonie mobile: I/Incidences de la distance et du sexe, Pathologie Biologie, Volume 50, Issue 6, 2002, Pages 369-373, ISSN 0369-8114, doi.org/10.1016/S0369-8114(02)00311-5.

[44] Gursatej Gandhi, Gurpreet Kaur & Uzma Nisar (2015) A cross-sectional case control study on genetic damage in individuals residing in the vicinity of a mobile phone base station, Electromagnetic Biology and Medicine, 34:4,344-354, DOI: 10.3109/15368378.2014.933349.

found at very low intensities of wireless radiation, including impacts on reproduction, permeability of the blood-brain barrier, behavior, cellular changes, and metabolic changes, and increases in cancer risk (Lai and Levitt 2010).[45]

- Published research has found impacts from wireless radiation exposure to reproduction and brain development in addition to a myriad of other adverse effects.[46,47,48,49] Although renowned institutions, such as the Cleveland Clinic, advise men to keep phones and wireless devices away from their reproductive organs, the public remains largely unaware.

Once the towers are erected, they will be upgraded over time with new antennas and soon 5G technology. 5G would use today's wireless frequencies while adding new, higher frequencies to transmit data at faster speeds. These higher frequency sub-millimeter waves are absorbed to a higher degree by the eyes and skin,[50,20,21,22] and have been shown to accelerate bacterial and viral cell growth.[51] Currently accepted standards are not sophisticated enough to quantify the risks of cumulative exposure.[52,53]Any future applications of these technologies must consider the biological effect of cumulative exposures to these frequencies.

"5G wireless telecommunications expansion: Public health and environmental implications," is a research review published in *Environmental Research*, which documents the range of adverse effects reported in the published literature, from cancer to bacteria growth changes to DNA damage, concludes that "a moratorium on the deployment of 5G is warranted" and "the addition of this added high-frequency 5G radiation to an already complex mix of lower frequencies, will contribute to a negative public health outcome both from both physical and mental health perspectives."[54]

Radiofrequency radiation exposure is increasing at a rapid pace.

A 2018 article published in *The Lancet Planetary Health* points to unprecedented increasing RF exposures, and the abstract concludes, "due to the exponential increase in the use of wireless personal

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[45] B. Blake Levitt and Henry Lai, Biological effects from exposure to electromagnetic radiation emitted by cell tower base stations and other antenna arrays, Environ. Rev. Downloaded from www.nrcresearchpress.com by 172.58.41.200 on 04/10/19

[46] Adams, Jessica A., et al. "Effect of mobile telephones on sperm quality: a systematic review and meta-analysis." *Environment International,* 70, 2014, pp. 106-112.

[47] Deshmukh, P.S., et al. "Cognitive impairment and neurogenotoxic effects in rats exposed to low-intensity microwave radiation." *International Journal of Toxicology*, vol. 34, no. 3, 2015, pp. 284-90.

[48] Aldad, T.S., et al. "Fetal Radiofrequency Radiation Exposure From 800-1900 MHz-Rated Cellular Telephones Affects Neurodevelopment and Behavior in Mice." *Scientific Reports,* vol. 2, no. 312, 2012.

[49] Sonmez, O.F., et al. "Purkinje cell number decreases in the adult female rat cerebellum following exposure to 900 MHz electromagnetic field." *Brain Research,* vol. 1356, 2010, pp. 95-101.

[50] A lecture by Paul Ben-Ishai, PhD at the Israel Institute for Advanced Studies on this finding can be found on the 2017 IIAS Conference website. Feldman, Yuri and Paul Ben-Ishai. "Potential Risks to Human Health Originating from Future Sub-MM Communication Systems." *Conference on Wireless and Health*, 2017.

[51] Cindy L. Russell, 5G Wireless Telecommunications Expansion: Public Health and Environmental Implications, 165 Envt'l Res. 484 (2018).

[52] A lecture by Paul Ben-Ishai, PhD at the Israel Institute for Advanced Studies on this finding can be found on the 2017 IIAS Conference website. Feldman, Yuri and Paul Ben-Ishai. "Potential Risks to Human Health Originating from Future Sub-MM Communication Systems." *Conference on Wireless and Health*, 2017.

[53] Hayut, Itai, Paul Ben Ishai, Aharon J. Agranat and Yuri Feldman. "Circular polarization induced by the three-dimensional chiral structure of human sweat ducts." *Physical Review E*, vol. 89, no. 042715, 2014.

[54] https://doi.org/10.1016/j.envres.2018.01.016

communication devices (eg, mobile or cordless phones and WiFi or Bluetooth-enabled devices) and the infrastructure facilitating them, levels of exposure to radiofrequency electromagnetic radiation around the 1 GHz frequency band, which is mostly used for modern wireless communications, have increased from extremely low natural levels by about 1018 times…"(Bandara and Carpenter, 2018).[55]

Another key finding from Zothansiama 2017 was that homes closer to antennas had measurably higher radiation levels—adding to the documentation that antennas increase RF levels. An Australian study also found that children in kindergartens with nearby antenna installations had nearly three-and-a-half times higher RF exposures than children with installations further away (more than 300 meters) (Bhatt 2016).[56]

A 2018 multi-country study that measured RF in several countries found that cell phone tower radiation is the dominant contributor to RF exposure in most outdoor areas exposure in urban areas was higher and that exposure has drastically increased. As an example, the measurements the researchers took in Los Angeles, USA was 70 times higher than the US EPA estimate 40 years ago.[57]

Telecommunications Companies Warn Their Shareholders

In fact, a number of corporations already advise their shareholders that they could face serious financial risks from the health damages due to RF. For instance, Crown Castle's 2019 10-K ANNUAL REPORT states that,

> If radio frequency emissions from wireless handsets or equipment on our communications infrastructure are demonstrated to cause negative health effects, potential future claims could adversely affect our operations, costs or revenues.
> The potential connection between radio frequency emissions and certain negative health effects, including some forms of cancer, has been the subject of substantial study by the scientific community in recent years. We cannot guarantee that claims relating to radio frequency emissions will not arise in the future or that the results of such studies will not be adverse to us.
> If a connection between radio frequency emissions and possible negative health effects were established, our operations, costs, or revenues may be materially and adversely affected. We currently do not maintain any significant insurance with respect to these matters.

Most wireless companies, from AT&T to Nokia to T Mobile to Verizon Wireless, have issued similar warnings to their shareholders. Why are shareholders being warned but not the people living near the equipment? These disclosures show that even corporations cannot assure safety.

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[55] Priyanka Bandara, David O Carpenter, Planetary electromagnetic pollution: it is time to assess its impact, *The Lancet Planetary Health*, Volume 2, Issue 12, 2018, Pages e512-e514,ISSN 2542-5196, doi.org/10.1016/S2542-5196(18)30221-3.
[56] Bhatt, C. R., Redmayne, M., Billah, B., Abramson, M. J., & Benke, G. (2016). Radiofrequency-electromagnetic field exposures in kindergarten children. *Journal Of Exposure Science And Environmental Epidemiology*, *27*, 497. Retrieved from https://doi.org/10.1038/jes.2016.55.
[57] Sanjay Sagar, Seid M. Adem, Benjamin Struchen, Sarah P. Loughran, Michael E. Brunjes, Lisa Arangua, Mohamed Aqiel Dalvie, Rodney J. Croft, Michael Jerrett, Joel M. Moskowitz, Tony Kuo, Martin Röösli, Comparison of radiofrequency electromagnetic field exposure levels in different everyday microenvironments in an international context, Environment International, Volume 114, 2018, Pages 297-306, ISSN 0160-4120, doi.org/10.1016/j.envint.2018.02.036.

Due to these evaluations and the published scientific evidence, cell phone manufacturers cannot insure against health damages from the radiofrequency radiation emitted by their products and networks. In fact, most insurance plans do not cover electromagnetic fields (EMF) and have very clear "electromagnetic field exclusions." In order for insurance companies to cover EMF, one often must purchase additional "Pollution Liability" or "Policy Enhancement" coverage.

According to CFC Underwriting LTD in London, the UK agent for Lloyd's:

> "The Electromagnetic Fields Exclusion (Exclusion 32) is a General Insurance Exclusion and is applied across the market as standard. The purpose of the exclusion is to exclude cover for illnesses caused by continuous long-term non-ionising radiation exposure i.e. through mobile phone usage."

Even AT&T Mobile Insurance excludes loss from "pollutants," and its policy defines "Pollutants" as "Any solid, liquid, gaseous, or thermal irritant or contaminant including smoke, vapor, soot, fumes, acid, alkalis, chemicals, artificially produced electric fields, magnetic field, electromagnetic field, sound waves, microwaves, and all artificially produced ionizing or non- ionizing radiation and waste" (pg. 4) AT &T Mobile Insurance Policy, February 2014.

If insurance companies will not insure EMF, and if even telecommunications companies consider EMF as a "pollutant," how can governments allow such an environmental pollutant without also warning their citizens as companies do?

5G Will Increase RF Exposures to the Environment and 5G Antenna Beamforming Exposures Cannot Be Accurately Measured

A 2019 European Parliament Report "5G Deployment: State of Play in Europe, USA, and Asia"[58] confirms increased exposure from the 5G/4G Densification, stating, "increased exposure may result not only from the use of much higher frequencies in 5G but also from the potential for the aggregation of different signals, their dynamic nature, and the complex interference effects that may result, especially in dense urban areas." The report points out that it currently "is not possible to accurately simulate or measure 5G emissions in the real world," stating,

> [T]he 5G radio emission fields are quite different to those of previous generations because of their complex beamformed transmissions in both directions – from base station to handset and for the return. Although fields are highly focused by beams, they vary rapidly with time and movement and so are unpredictable, as the signal levels and patterns interact as a closed loop system. This has yet to be mapped reliably for real situations, outside the laboratory.

[58] BLACKMAN, C. and FORGE, S. (2019). *5G Deployment State of Play in Europe, USA and Asia*. [PDF] European Parliament's Committee on Industry, Research and Energy. Available at: https://www.europarl.europa.eu/RegData/etudes/IDAN/2019/631060/IPOL_IDA(2019)631060_EN.pdf [Accessed 24 Feb. 2020].

A 2018 study published in Annals of Telecommunications found increased RF-EMF exposure from small cell LTE networks in two urban cities in France and the Netherlands. Researchers measured the RF-EMF from LTE (Long-Term Evolution), MC (macro cells meaning large cell towers), and SC networks (low-powered small cell base stations) and found that the small cell networks increased the radio emissions from base stations (called downlink) by a factor of 7–46 while decreasing the radio emissions from user equipment exposure (called uplink) by a factor of 5–17. So while the devices themselves could emit less radiation, the cell antennas will increase the ambient environmental levels (Mazloum et al., 2019). This study shows the increased exposures would be involuntary. We can turn our phones off, but we cannot turn off the antennas in the neighborhood. The birds, bees, and trees have no choice.

Thank you for your consideration of this issue. We would like to set up a phone call to discuss this issue further.

Sincerely,

Devra Davis, PhD, MPH
Fellow, American College of Epidemiology
Visiting Prof. Hebrew Univ. Hadassah Medical Center & Ondokuz Mayis Univ. Medical School
Associate Editor, Frontiers in Radiation and Health
President, Environmental Health Trust

Theodora Scarato
Executive Director, Environmental Health Trust

Letter from the EPA

--------- Forwarded message ---------
From: **Veal, Lee**<Veal.Lee@epa.gov>
Date: Wed, Jul 8, 2020 at 11:32 AM
Subject: RE: Letter with specific Questions Related to the FDA review and to the EPA, CDC, NIOSH and FDA Jurisdiction on EMFs
To: Theodora Scarato <Theodora.Scarato@ehtrust.org>

Dear Director Scarato;

Thank you for sending us your questions and references regarding radiofrequency (RF) radiation. Up through the mid-1990s, EPA did study non-ionizing radiation. The Telecommunications Act of 1996 directs the Federal Communications Commission (FCC) to establish rules regarding RF exposure, while the U.S. Food and Drug Administration (FDA) sets standards for electronic devices that emit non-ionizing or ionizing radiation. EPA does not have a funded mandate for radiofrequency matters, nor do we have a dedicated subject matter expert in radiofrequency exposure. The EPA defers to other agencies possessing a defined role regarding RF. Although your questions are outside our current area of responsibilities, we have provided a response to each one as you requested.

1. *What is your response to these scientists' statements regarding the FDA report and the call to retract it?*

   EPA Response: The EPA does not have a funded mandate for radiofrequency matters, has not conducted a review of the FDA report you cited or the scientists' statements, and therefore has no response to it.

2. *To the FDA- What consultants were hired for the FDA review and report on cell phone radiation?*

   EPA Response: This is not an EPA matter. Please refer this question to the FDA.

3. *What US agency has reviewed the research on cell phone radiation and brain damage? I ask this because the FDA only has looked at selected studies on cancer. If your agency has not, please simply state you have not.*

   EPA Response: EPA's last review was in the 1984 document Biological Effects of Radiofrequency Radiation (EPA 600/8-83-026F). The EPA does not currently have a funded mandate for radiofrequency matters.

4. What US agency has reviewed the research on damage to memory by cell phone radiation? If so, when and send a link to the review.

   EPA Response: EPA's last review was in the 1984 document Biological Effects of Radiofrequency Radiation (EPA 600/8-83-026F). The EPA does not currently have a funded mandate for radiofrequency matters.

5. *What US agency has reviewed the research on damage to trees from cell phone radiation? If so, when was it issued and send a link to the review.Note this study showing damage from long term exposure to cell antennas.*

   EPA Response: The EPA does not have a funded mandate for radiofrequency matters, and we are not aware of any EPA reviews that have been conducted on this topic. We do not know if any other US agencies have reviewed it.

6. *What US agency has reviewed the research on impacts to birds and bees? If so, when and send a link to the review. I will note the latest research showingpossible impacts to bees from higher frequencies to be used in 5G.*

   EPA Response: The EPA does not have a funded mandate for radiofrequency matters, and we are not aware of any EPA reviews that have been conducted on this topic. We do not know if any other US agencies have reviewed it.

7. *What is a safe level of radiofrequency radiation? I ask this because the FDA and FCC both state they do not need to test cell phones at body contact and it is proven that phones will create exposure that are higher than FCC limits when phones are tested in these positions.*

   The Telecommunications Act of 1996 directs the FCC to establish rules regarding radiofrequency (RF) exposure.The U.S. Food and Drug Administration (FDA) sets standards for electronic devices that emit non-ionizing or ionizing radiation. The EPA defers to these regulatory authorities for the establishment of safe levels of radiofrequency radiation.

8. *The FDA and FCC have been provided with information and published data showing the fact that cell phones create cell phone radiation exposures that violate FCC limits. What agency has the job of ensuring accountability that the American public is not exposed to RF radiation that exceeds FCC limits. The FCC has test protocols that say body contact tests are not needed. The*

FDA refers to the FCC. Yet the fact is that cell phones exceed FCC limits when tested in body contact positions. Are the FCC limits legitimate? These FCC limits are being violated. Who is the responsible agency that will ensure Americans are protected? The FCC says their rules are not being violated as their rules allow for a space between the phone or device and the body? The FDA says there is a safety factor so there is no need for them to act (and will not state what the safety factor for a cell phone is) . YET government limits are being exceeded. Are agencies fine with limits being violated? If so please explain at what level of cell phone radiation a federal agency will step in? If so, which agency has jurisdiction? (March 12, 2019 Publication on Om Gandhi's paper on radiation emissions violating FCC limits 11 times and August 21, 2019 Chicago Tribune cell phone testing data released)

EPA Response: The Telecommunications Act of 1996 directs the FCC to establish rules regarding radiofrequency (RF) exposure. The U.S. Food and Drug Administration (FDA) sets standards for electronic devices that emit non-ionizing or ionizing radiation. The EPA does not have a funded mandate for radiofrequency matters, and the questions you raise are outside of EPA's areas of responsibilities and current expertise. Please refer this question to FCC and FDA.

9. *The National Toxicology Program states clear evidence of cancer was found and the FDA disputes this because it was just an animal study. However birds fly and nest on cell antennas mounted on towers, bees fly in front of antennas and family pets (dogs, cats) will sit directly on or near Wi-Fi routers and smart speakers despite the fact that the manuals state humans should be at a minimum of 20 cm from wireless devices (far more from antennas of towers). What about the impact to these animals? What is the US government doing to ensure safety for wildlife and family pets?*

EPA Response: The EPA does not have a funded mandate for radiofrequency matters, and the questions you raise are outside of EPA's area of responsibility and current expertise. We defer to FDA to provide a response regarding their findings.

10. *Please send me the staff member of your respective agency who is on the Interagency Radiofrequency Workgroup as I have repeatedly tried to get this information and it is never provided to me.*

EPA Response: The Radiofrequency Interagency Work Group (RFIAWG) is an informal forum for exchange of information and the group does not meet to set, or advise on, policy, rulemaking or guidance. The group has not met in more than two years.

11. *The FDA only reviewed selected studies on cancer until 2018. Most recently, the American Cancer Society funded* radiation in*people with genetic susceptibilities. The National Toxicology Program published research showing DNA damage. Will the FDA be updating it's review with these studies? If not, then what agency is accountable to American public to ensure humans are not harmed?*

EPA Response: The questions you raise are outside of EPA's areas of responsibilities and current expertise. Please direct questions about FDA activities to FDA.

12. *What agency ensures safety related to extremely low frequency (ELF-EMF) electromagnetic fields- also non ionizing? Currently we have no federal limit, no federal guidelines and confirmed associations with cancer and many other health effects. Kaiser Permanente researchers have published several studies linking pregnant women's exposure to magnetic field electromagnetic fields to not only increased miscarriage and but also increased ADHD, obesity and asthma in the woman's prenatally exposed children. A recent large scale study again found associations with cancer. Please clarify which US agency has jurisdiction over ELF-EMF exposures?*

EPA Response: There are no U.S. Federal standards limiting residential or occupational exposure to electric and magnetic fields (EMF) from power lines. The EPA does not have a funded mandate for radiofrequency matters.

13. When it comes to cell phone radiation SAR thresholds, what is your understanding of the "safety factor" in place?

EPA Response: EPA last commented on FCC proposals for SAR limits in the 1996FCC 96-236. The Telecommunications Act of 1996 directs the FCC to establish rules regarding radiofrequency (RF)

exposure.The U.S. Food and Drug Administration (FDA) sets standards for electronic devices that emit non-ionizing or ionizing radiation. The EPA defers to these regulatory authorities for the establishment of safe levels of radiofrequency radiation.

Sincere regards,

Lee Ann B. Veal

Director, Radiation Protection Division

Office of Radiation and Indoor Air

www.epa.gov/radiation

Letters to And From Councilwoman Denise Ricciardi of the New Hampshire Commission on 5G
to Dr. Barrington and Dr. Hoover of the National Cancer Institute

Begin forwarded message:

From: NCI Information <nciinfo@nih.gov>
Date: July 30, 2020 at 2:51:16 PM EDT
To: Denise Ricciardi <dricciardi@bedfordnh.org>
Subject: Important questions that need to be answered.
Reply-To: "NCI Information" <nciinfo@nih.gov>

Subject

Important questions that need to be answered.

Response By Email (NCI Agent) (07/30/2020 11:51 AM)
Dear Ms. Ricciardi:

I received your follow-up inquiry requesting an answer to each question listed in your email. Please see below:

1.What is the National Cancer Institute opinion on the safety of 5G, 4G and cell towers? If you have one, please share your scientific documentation.

As a Federal research agency, the NCI is not involved in the regulation of radiofrequency telecommunications infrastructure and devices, nor do we make recommendations for policies related to this technology. The Food and Drug Administration (FDA) and the Federal Communications Commission (FCC) are the responsible federal agencies with authority to issue opinions on the safety of these exposures. Rather, NCI gathers and reviews published findings of well-conducted studies with a focus on cancer in humans in the medical literature and makes summaries available on its website and fact sheets.

According to the FCC<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.fcc.gov_engineering-2Dtechnology_electromagnetic-2Dcompatibility-2Ddivision_radio-2Dfrequency-2Dsafety_faq_rf-2Dsafety-23Q26&d=DwMGaQ&c=eRAMFD45gAfqt84VtBcfhQ&r=q4b8W6TEfORbK_PCSF6-YgGPnscor-y8wRNq0YfDRIw&m=iGygvfH1o3HmfSTdr3x_k1F2peLnrVj-6qkVMXK6iIw&s=kAsjtCua4lQ5CBV_eFbNpaFUSGVj83yJBRwtcdwPh2E&e=>, certain agencies in the Federal Government have been involved in monitoring, researching or regulating issues related to human exposure to radiofrequency radiation. These agencies include the FDA, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safe and Health (NIOSH), the National Telecommunications and Information Administration (NTIA) and the Department of Defense (DOD).

2.Has NCI staff done a systematic research review of the research on wireless radiation?

Experts at the NCI review the research on radiofrequency radiation and other types of non-ionizing radiation electromagnetic fields (EMFs) in order to maintain our fact sheets on these topics. Other federal agencies have the responsibility to formally review the research on these exposures, specifically the FDA and FCC.

3.What is the NCI opinion on the safety of cell phones? If you have one, please share your scientific documentation.

The FDA and FCC are the responsible federal agencies with authority to issue opinions on the safety of these exposures. As a Federal research agency, the NCI is not involved in the regulation of radiofrequency telecommunications infrastructure and devices, nor do we make recommendations for policies related to this technology.

The NCI gathers and reviews published findings of well-conducted studies in the medical literature on cell phones and cancer risk. The NCI fact sheet "Cell Phones and Cancer Risk<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.cancer.gov_about-2Dcancer_causes-2Dprevention_risk_radiation_cell-2Dphones-2Dfact-2Dsheet&d=DwMGaQ&c=eRAMFD45gAfqt84VtBcfhQ&r=q4b8W6TEfORbK_PCSF6-YgGPnscor-y8wRNq0YfDRIw&m=iGygvfH1o3HmfSTdr3x_k1F2peLnrVj-6qkVMXK6iIw&s=MZJiSB8dkF4_O3u6NE8f2CZWkqc4mHm8ECgWM9hkRIk&e=>" outlines the available evidence from human and animal studies regarding cancer risk and cell/mobile telephones. It includes references and the citations are at the bottom of the document.

4.Does the NCI recommend that parents teach their children to reduce exposure to cell phone radiation? Does the NCI think it is not necessary to take precautions and that information on reducing exposure is only for "concerned" people? Or does the NCI recommend all parents educate their children to reduce exposure and that they themselves reduce exposure to their children?

As noted above, the NCI does not make recommendations or issue guidelines. The fact sheet "Cell Phones and Cancer Risk" does include information from the FDA about ways cell phone users—children, teenagers or adults—can reduce their exposure to radiofrequency radiation. The FDA suggests that cell phone users reserve the use of cell phones for shorter conversations or for times when a landline phone is not available; and use a device with hands-free technology, such as wired headsets, which place more distance between the phone and the head of the user.

5.Did the NCI review in a systematic way the research on impacts of wireless and cell towers to trees and plants? If not, what agency is responsible for ensuring wireless signals are safe for trees and plants?

The NCI is not charged with researching the impact of wireless technology and cell towers on trees and plants. NCI is not aware of any Federal agency mandated to ensure wireless signals are safe for trees and plants.

6.Did the NCI review in a systematic way the research on cell towers and how wireless antennas impact birds. If not, what agency is responsible for ensuring wireless signals are safe for birds?

The NCI is not charged with researching the impact of wireless technology and cell towers on birds. The NCI is not aware of any Federal agency mandated to ensure wireless signals are safe birds.

7.Did the NCI review in a systematic way the research on impact to bees and insects. If not, what agency is responsible for ensuring wireless signals are safe for insects and bees?

The NCI is not charged with researching the impact of wireless technology on bees and other insects. The NCI is not aware of any Federal agency mandated to ensure wireless signals are safe for bees and other insects.

8. Does the NCI only focus on cancer as a health effect?

Yes. In addition, by law, U.S. population-based cancer registries must collect information on benign brain tumors and the NCI fact sheet "Cell Phones and Cancer Risks" describes findings for meningioma, acoustic neuroma and other benign brain and central nervous system tumors.

9.The NCI does not present the findings of the NTP as "clear evidence of cancer" but simply states of the findings that "The primary outcomes observed were a small number of cancers of Schwann cells in the heart and non-cancerous changes (hyperplasia>) in the same tissues for male rats, but not female rats, nor in mice overall." Why doesn't the NCI present the findings of DNA damage on their webpage as it is published and was found in rats and mice. In addition cardiomyopathy was found. Why isn't this presented on the NCI webpage?

The focus of the fact sheet "Cell Phones and Cancer Risk" is limited to cancer risk. As you noted, the fact sheet provided an overview of the primary outcomes found in the National Toxicology Program (NTP) study. These findings are reported on the NTP website<https://urldefense.proofpoint.com/v2/url?u=https-3A__ntp.niehs.nih.gov_whatwestudy_topics_cellphones_index.html&d=DwMGaQ&c=eRAMFD45gAfqt84VtBcfhQ&r=q4b8W6TEfORbK_PCSF6-YgGPnscor-y8wRNq0YfDRIw&m=iGygvfH1o3HmfSTdr3x_k1F2peLnrVj-6qkVMXK6iIw&s=C5W0B6y6dOOOf9L7t9_YymXKp7CRBYHIvy8XZVi4Lkc&e=>. A link to this information was included in the fact sheet for those who wish to know more about the NTP study.

10.The FDA disagrees with the National Toxicology Program findings of clear evidence of cancer. What is the NCI position on the determination of "clear evidence"?

The NCI does not comment on the cancer evaluation criteria of other organizations or how researchers use these definitions in their analysis. You may find useful a critical evaluation of the NTP study<mailto:https//journals.lww.com/health-physics/Fulltext/2020/05000/ICNIRP_Note__Critical_Evaluation_of_Two.3.aspx>; that was conducted by the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

11.Is there evidence that heating can cause cancer? That elevated temperatures can induce cancer?

There is no current evidence<https://www.cancer.gov/about-cancer/causes-prevention/risk> that elevated temperatures or heating is a risk factor for cancer.

12.Has the NCI reviewed in a systematic way the research on impacts to the nervous system?

The NCI fact sheet on "Cell Phones and Cancer Risk" provides a summary review of most epidemiologic studies of cell phone use and brain and other central nervous system tumors. Most of the studies are case-control studies. Details are provided on the three most impactful studies, including the 13-country,

case-control Interphone study, the large national Danish cohort study, and the Million Women United Kingdom cohort study.

13.Does the NCI believe the current limits protect the public, children, pregnant women and medically vulnerable from health effects after long term exposure. Please provide documentation for each group, children, pregnant women and medically vulnerable that shows research ensuring safety.

The NCI does not regulate issues related to human exposure to radiofrequency radiation.

14.We know that the NCI is aware that cell phones can violate FCC SAR limits at body contact on high power. The FDA has written that because there is a safety factor. What is the safety factor for the SAR the FDA relies on? Do you know?

The FDA shares regulatory responsibilities for cell phones with the FCC. The FCC certifies wireless devices, and all phones that are sold in the United States must comply with FCC guidelines on radiofrequency exposure. The FDA also has the authority to take action if cell phones are shown to emit radiofrequency energy at a level that is hazardous to the user.

In addition, the FDA is responsible for protecting the public from harmful radiation emissions from consumer products such as microwave ovens, televisions, and computer monitors. You may wish to contact the FDA's Center for Devices and Radiological Health's Office of Compliance at 301–594–4654, for information about SAR guidelines used in cell phones.

15. Will the NCI be taking action to inform the public about this? If not, please explain why not.

NCI staff are committed to regularly reviewing the published findings of well-conducted studies on cancer and making them available on a timely basis to the public through our online fact sheets. As noted above, the NCI continues to make this information available on its website Cancer.gov, the Institute's primary resource in informing the public about cancer research. The NCI gathers and reviews published findings of well-conducted studies in the medical literature on cell phones and cancer risk. The NCI fact sheet "Cell Phones and Cancer Risk" outlines the available evidence from human and animal studies regarding cancer risk and cell/mobile telephones. As also noted above, the NCI has conducted a review of the research on radiofrequency radiation and other types of non-ionizing radiation electromagnetic fields (EMFs), available in the fact sheet "Electromagnetic Fields and Cancer." NCI will continue to update these factsheets as new relevant studies are published in the per-reviewed literature.

Our sister agencies, the FDA as well as the FCC, retain responsibility for reviewing guidance on safety concerns and informing the public if those circumstances change.

16.What actions specifically is the NCI doing now in regards to 5G and cell phone radiation in terms of research review?

As noted above, the NCI regularly reviews the published findings of studies on cancer and makes them available to the public.

Additionally, given the multi-year latency of brain tumors and most other solid tumors and the need to carefully consider the optimal study design, it would be premature to begin development of a protocol for studying the relation between 5G exposures and cancer risk before 5G systems are implemented. We

are in close communication with other epidemiologists and dosimetrists working on radiofrequency exposures and cancer risks. We continue to carefully monitor research in this area.

17.Does the NCI evaluate the safety of 5G cell antennas? If so how? If not, what health agency is ensuring that 5G cell antennas are safe for people, wildlife and trees.

The FCC is responsible for developing guidelines for human exposure to radiofrequency electromagnetic fields, which includes antennas.

18.Cell phones and wireless devices emit several types of nonionizing radiation in addition to radiofrequency radiation. For example the devices emit magnetic fields and when a pregnant woman holds a laptop on her lap the measured fields can be high even into the baby. What agency ensures safety related to extremely low frequency (ELF-EMF) electromagnetic fields- also nonionizing? Currently we have no federal limit, no federal guidelines and confirmed associations with cancer and many other health effects. Kaiser Permanente researchers have published several studies linking pregnant women's exposure to magnetic field electromagnetic fields to not only increased miscarriage> and but also increased ADHD>, obesity> and asthma> in the woman's prenatally exposed children. A recent large-scale study #> again found associations with cancer. Where is the NCI presentation of this research for the public?

As noted above, the FDA is responsible for protecting the public from radiation emissions from consumer products such as microwave ovens, televisions, and computer monitors. You may wish to contact the FDA's Center for Devices and Radiological Health's Office of Compliance at 301–594–4654, for information about research on this topic.

Our sister institute, National Institute of Child Health and Human Development (NICHD)<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.nichd.nih.gov_&d=DwMGaQ&c=eRAMFD45gAfqt84VtBcfhQ&r=q4b8W6TEfORbK_PCSF6-YgGPnscor-y8wRNq0YfDRIw&m=iGygvfH1o3HmfSTdr3x_k1F2peLnrVj-6qkVMXK6iIw&s=0DL2MeSKqAe02BKmMIIU4OQ13tnkrCsK-T4hCiej5Wo&e=>, another part of the NIH, investigates human development throughout the entire life process, with a focus on understanding disabilities and important events that occur during pregnancy. You may wish contact to the NICHD for information about radiofrequency radiation exposure and human development. NICHD can be contacted by email at NICHDInformationResourceCenter@mail.nih.gov<mailto:NICHDInformationResourceCenter@mail.nih.gov>.

NCI staff are committed to regularly reviewing the published findings of well-conducted studies on cancer and making them available on a timely basis to the public through our online fact sheets.

19.Will the NCI be sharing and recommending how to reduce ELF- EMF Exposure?
Please clarify which US agency has jurisdiction over ELF-EMF exposures?
Please clarify which US agency has authority to set limits for ELF-EMF exposures? As far as we know there is no limit in the USA for this type of exposure.

According to the fact sheet "Electromagnetic Fields and Cancer<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.cancer.gov_about-2Dcancer_causes-2Dprevention_risk_radiation_electromagnetic-2Dfields-2Dfact-2Dsheet&d=DwMGaQ&c=eRAMFD45gAfqt84VtBcfhQ&r=q4b8W6TEfORbK_PCSF6-YgGPnscor-y8wRNq0YfDRIw&m=iGygvfH1o3HmfSTdr3x_k1F

2peLnrVj-6qkVMXK6ilw&s=C0NXYMLf0A6r2vL1wAnjf5vpVZsukPH0691HEXK03vY&e=>" sources of ELF-EMFs include power lines, electrical wiring, and electrical appliances such as shavers, hair dryers, and electric blankets.

As noted above, the NCI is not responsible for setting limits for ELF-EMF or any other exposure. Manufacturers of electronic radiation emitting products sold in the United States are responsible for compliance with the Federal Food, Drug and Cosmetic Act (FD&C Act), Chapter V<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.fda.gov_RegulatoryInformation_LawsEnforcedbyFDA_FederalFoodDrugandCosmeticActFDCAct_FDCActChapterVDrugsandDevices_default.htm&d=DwMGaQ&c=eRAMFD45gAfqt84VtBcfhQ&r=q4b8W6TEfORbK_PCSF6-YgGPnscor-y8wRNq0YfDRIw&m=iGygvfH1o3HmfSTdr3x_k1F2peLnrVj-6qkVMXK6ilw&s=GsniD-gspsAWvWaULzmKKorN8XfEL7B69W-pmYZ3ucY&e=>, Subchapter C - Electronic Product Radiation Control.

The U.S. Congress created the National Institute of Environmental Health Sciences' (NIEHS) EMF Research and Public Information Dissemination (RAPID) Program in 1992 to study whether exposure to EMFs produced by the generation, transmission, or use of electric power posed a risk to human health. Although this program has ended, the NIEHS continues to study EMFs. For more information, please see the NIEHS website<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.niehs.nih.gov_health_topics_agents_emf_&d=DwMGaQ&c=eRAMFD45gAfqt84VtBcfhQ&r=q4b8W6TEfORbK_PCSF6-YgGPnscor-y8wRNq0YfDRIw&m=iGygvfH1o3HmfSTdr3x_k1F2peLnrVj-6qkVMXK6ilw&s=zNttXtXOSnUfwWXebzTrydT1H8RlpYMQvsid71IjquI&e=>.

20.Who are the NCI staff who have expertise on this issue at the NCI? What NCI staff is in the Interagency workgroup and where can we access the minutes and work of this group?

The content on the NCI's website Cancer.gov related to this topic is authored and maintained by NCI staff. The information on this site is science-based, authoritative, and up to date. Medical experts, cancer researchers, and editors review the content before it is published to the website.

Within the NCI, several research divisions conduct or fund extramural research to discover the genetic and environmental determinants of cancer and new approaches to cancer prevention, including the impacts of ionizing and nonionizing radiation. Epidemiologists also monitor cancer incidence trends for potentially relevant malignancies using U.S.-based cancer registries such as the North American Association of Central Cancer Registries and the Surveillance, Epidemiology, and End Results Program, and periodically review the scientific peer-reviewed literature in this area.

If you are compiling a list of EMF experts to contact, it is important to note that NCI scientists receive many requests for interviews or for advice with projects. All such inquiries should be directed to the NCI Office of Communications and Public Liaison through the NCI contact page<mailto:https//www.cancer.gov/contact>; found on Cancer.gov.

21.The FCC decided not to update their limits on wireless but the NCI did not submit an opinion to the FCC. Why not?

As noted above, the NCI does not make recommendations for policies on wireless technology.

22.Will the NCI be submitting an opinion to the FCC about the higher frequencies to be used in 5G?

As noted above, the NCI does not make recommendations for policies on wireless technology.

23. The American Cancer Society funded research by Yale that found cancer after cell phone radiation exposure. See it here https://medicine.yale.edu/news-article/22332/<https://protect-us.mimecast.com/s/K3TvCmZnOMf1oANt4_6HQ/>What is the NCI opinion?

NCI staff are committed to regularly reviewing the published findings of well-conducted studies on cancer and making them available on a timely basis to the public through our online fact sheets.

24. Will you be updating your webpage with information on thyroid cancer and on genetic susceptibility as found by the Yale study?

NCI staff are committed to regularly reviewing the published findings of well-conducted studies on cancer and making them available on a timely basis to the public through our online fact sheets.

Sincerely yours,

Bill Robinson
Office of Communications and Public Liaison
National Cancer Institute

Customer By CSS Email (Denise Ricciardi) (07/19/2020 06:55 AM)
Hello,
You did not satisfy the commission. We requested you answer each question point by point. Not a paragraph that does NOT properly answer the questions.

Please go back and answer the questions number one provide the answer number two provide the answer and so on. Please expedite this request, it is urgent for commission.

Thank you,
Denise Ricciardi

[External]

_____
[Image]

Subject

Important questions that need to be answered.

Response By Email (NCI Agent) (07/16/2020 11:39 AM)
Dear Ms. Ricciardi:

Your email to Dr. Amy Berrington and Dr. Robert Hoover of the National Cancer Institute (NCI) regarding 5G has been forwarded to this office for reply. In your email, you asked questions about the status of research of the health and environmental effects of 5G (fifth-generation) wireless network technology on people and the natural world and which Federal agencies regulate this technology. We can offer information that you may find useful.

The NCI, part of the National Institutes of Health, is the Federal government's principal agency for cancer research and training. Part of the NCI's mission includes gathering and disseminating information about cancer, including risk factors, to the public and medical community through its website, fact sheets, and the NCI's Cancer Information Service (CIS). The fact sheets "Cell Phones and Cancer Risk" and "Electromagnetic Fields and Cancer" outline the available evidence from human and animal studies regarding cancer risk and cellular/mobile telephones and low- to medium-frequency electromagnetic fields.

The National Toxicology Program (NTP) investigated the health effects in animals exposed to radiofrequency (RF) radiation modulations used in 2G and 3G cell phones. According to the lead toxicologist of the studies, Michael Wyde, Ph.D., "5G is an emerging technology that hasn't really been defined yet. From what we currently understand, it likely differs dramatically from what we studied." This comment can be found in the NIH news release about the NTP final reports.

The NCI is committed to reviewing published findings of well-conducted studies in the medical literature and making them available to the public. Sometimes the results of a research study can yield inconsistent and even unanticipated results. Nonetheless, in this way, hypotheses are thoroughly evaluated.

As a Federal research agency, the NCI does not regulate RF electromagnetic field (EMF) exposure or establish guidelines. Within the Federal government, the U.S. Federal Communications Commission (FCC) authorizes or licenses most RF telecommunications services, facilities, and devices used by the public, industry and state and local governmental organizations. The FCC is required by the National Environmental Policy Act of 1969, among other things, to evaluate the effect of EMF emissions from FCC-regulated transmitters on the quality of the human environment. This includes cell phones and towers. The FCC Policy on Human Exposure web page includes links to several organizations that have recommendations for human exposure to EMF.

In addition, the U.S. Food and Drug Administration (FDA) shares regulatory responsibilities for cell phones with the FCC. Although cell phones can be sold without FDA clearance or approval, the agency monitors the effects the phones have on health. The FDA has the authority to take action if cell phones are shown to emit RF energy at a level that is hazardous to the user. The FDA recently provided an updated assessment of the current limits of RF energy based on the currently available scientific evidence (see Letter from the FDA to the FCC on Radiofrequency Exposure).

Sincerely yours,

Bill Robinson
Office of Communications and Public Liaison
National Cancer Institute

Customer By CSS Email (Denise Ricciardi) (07/10/2020 07:25 AM)

Hello,

I serve in New Hampshire on a health study commission. We need these questions answered each one, one by one.

Questions to Dr. Barrington and Dr. Hoover of the National Cancer Institute

1.What is the National Cancer Institute opinion on the safety of 5G, 4G and cell towers? If you have one please share your scientific documentation.
2.Has NCI staff done a systematic research review of the research on wireless radiation?
3.What is the NCI opinion on the safety of cell phones? If you have one please share your scientific documentation.
4.Does the NCI recommend that parents teach their children to reduce exposure to cell phone radiation? Does the NCI think it is not necessary to take precautions and that information on reducing exposure is only for "concerned" people? Or does the NCI recommend all parents educate their children to reduce exposure and that they themselves reduce exposure to their children?
5.Did the NCI review in a systematic way the research on impacts of wireless and cell towers to trees and plants? If not what agency is responsible for ensuring wireless signals are safe for trees and plants?
6.Did the NCI review in a systematic way the research on cell towers and how wireless antennas impact birds. If not, what agency is responsible for ensuring wireless signals are safe for birds?
7.Did the NCI review in a systematic way the research on impact to bees and insects. If not, what agency is responsible for ensuring wireless signals are safe for insects and bees?
8. Does the NCI only focus on cancer as a health effect?
9.The NCI does not present the findings of the NTP as “clear evidence of cancer” but simply states of the findings that” The primary outcomes observed were a small number of cancers of Schwann cells in the heart and non-cancerous changes (hyperplasia>) in the same tissues for male rats, but not female rats, nor in mice overall.” Why doesn’t the NCI present the findings of DNA damage on their webpage as it is published and was found in rats and mice. In addition cardiomyopathy was found. Why isn’t this presented on the NCI webpage?
10.The FDA disagrees with the National Toxicology Program findings of clear evidence of cancer. What is the NCI position on the determination of “clear evidence”?
11.Is> there evidence that heating can cause cancer? That elevated temperatures can induce cancer?
12.Has the NCI reviewed in a systematic way the research on impacts to the nervous system?
13.Does the NCI believe the current limits protect the public, children, pregnant women and medically vulnerable from health effects after long term exposure. Please provide documentation for each group, children, pregnant women and medically vulnerable that shows research ensuring safety.
14.We know that the NCI is aware that cell phones can violate FCC SAR limits at body contact on high power. The FDA has written that because there is a safety factor. What is the safety factor for the SAR the FDA relies on. Do you know?
15. Will the NCI be taking action to inform the public about this? If not, please explain why not.
16.What actions specifically is the NCI doing now in regards to 5G and cell phone radiation in terms of research review?
17.Does the NCI evaluate the safety of 5G cell antennas? If so how? If not, what health agency is ensuring that 5G cell antennas are safe for people, wildlife and trees.
18.Cell phones and wireless devices emit several types of non ionizing radiation in addition to radiofrequency radiation. For example the devices emit magnetic fields and when a pregnant woman holds a laptop on her lap the measured fields can be high even into the baby. What agency ensures safety related to extremely low frequency (ELF-EMF) electromagnetic fields- also non ionizing? Currently

we have no federal limit, no federal guidelines and confirmed associations with cancer and many other health effects. Kaiser Permanente researchers have published several studies linking pregnant women's exposure to magnetic field electromagnetic fields to not only increased miscarriage> and but also increased ADHD>, obesity> and asthma> in the woman's prenatally exposed children. A recent large scale study #> again found associations with cancer. Where is the NCI presentation of this research for the public?

19.Will the NCI be sharing and recommending how to reduce ELF- EMF Exposure?

Please clarify which US agency has jurisdiction over ELF-EMF exposures?

Please clarify which US agency has authority to set limits for ELF-EMF exposures? As far as we know there is no limit in the USA for this type of exposure.

20.Who are the NCI staff who have expertise on this issue at the NCI?

What NCI staff is in the Interagency workgroup and where can we access the minutes and work of this group?

21.The FCC decided not to update their limits on wireless but the NCI did not submit an opinion to the FCC. Why not?

22.Will the NCI be submitting an opinion to the FCC about the higher frequencies to be used in 5G.

23. The American Cancer Society funded research by Yale that found thyroid cancer after cell phone radiation exposure. See it here https://medicine.yale.edu/news-article/22332/<https://protect-us.mimecast.com/s/K3TvCmZnOMf1oANt4_6HQ/> What is the NCI opinion?

24. Will you be updating your webpage with information on thyroid cancer and on genetic susceptibility as found by the Yale study?

Thank you for your cooperation.

Denise Riccciardi

Letters to And From Councilwoman Denise Ricciardi of the New Hampshire Commission on 5G to Dr. Shuren of the FDA

On Jul 15, 2020, at 5:31 PM, Meister, Karen G <Karen.Meister@fda.hhs.gov> wrote:

[External]

Dear Ms. Ricciardi,

Thank you for contacting the Food & Drug Administration (FDA) with your concerns regarding exposure to non-ionizing electromagnetic energy. Your inquiry was forwarded to the Intergovernmental Affairs (IGA) team in the Office of the Commissioner. We understand that you are a member of New Hampshire's "Commission to Study the Environmental and Health Effects of Evolving 5G Technology," and that you are gathering information.

As you may know, FDA shares regulatory responsibilities for cell phones with the Federal Communications Commission (FCC). Under the law, FDA is responsible for, among other things: consulting with other federal agencies on techniques and programs for testing and evaluating electronic product radiation and collecting, analyzing, and making available scientific information on the nature and extent of the hazards and control of electronic product radiation. FDA's website provides information about cell phones, including the Agency's current assessment on the safety of exposure to non-ionizing electromagnetic fields. See https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell-phones<https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell-phones>. The website includes an update to the scientific evidence evaluated by FDA (see https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety<https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety>) , as well as suggestions for those that may still be concerned about non-ionizing energy exposure (see https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure-cell-phones<https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure-cell-phones>).

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FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects. FDA also works with national and international health agencies to ensure the weight of scientific evidence is appropriately evaluated.

We hope this information is helpful to answer your questions.

Best regards.

Karen

Karen Meister, J.D.
Acting Director, Intergovernmental Affairs
Senior Advisor, Office of Legislation
Office of the Commissioner/OPPLIA
U.S. Food and Drug Administration
(301) 796-8916 office
(240) 494-6228 (work cell)

----Original Message-----

From: Denise Ricciardi <dricciardi@bedfordnh.org<mailto:dricciardi@bedfordnh.org>>

Sent: Tuesday, June 23, 2020 10:38 PM

To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov<mailto:Jeff.Shuren@fda.hhs.gov>>

Cc: OC Ombudsman <Ombuds@OC.FDA.GOV<mailto:Ombuds@OC.FDA.GOV>>; Patrick Abrami <abrami.nhrep@gmail.com<mailto:abrami.nhrep@gmail.com>>

Subject: Important questions NEED to be answered for N.H. 5G health task commission

Dear Dr. Shuren,

We would appreciate an answer to these questions regarding cell phone radiation. If you could number them one by one it would help with clarity of your response.

Regarding the FDAs report “Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and
Cancer<https://www.fda.gov/media/135043/download<https://www.fda.gov/media/135043/download>>

1. Why did the FDA only focus on cancer as a health effect?

2. The FDA said of the National Toxicology Program findings that the FDA was unsure if the tumors were a causal effect or if these results were “due to weakening of the immune response due to animal stress from cyclic heating and thermoregulation”Does the FDA think that cancer could be an effect of whole body heating, that cancer is a thermally induced effect? If so, what other studies show that heating causes cancer?

3. Did the FDA review in a systematic way the research on impacts to the nervous system?

4. At the Commission, a study on how millimeter waves interact with insects was discussed. Did the FDA review in a systematic way the research on impact to bees, insects and pollinators?

5. Did the FDA review in a systematic way the research on impact to trees and plants?

6. Did the FDA review in a systematic way the research on impact to birds.

7. If the FDA did not investigate impacts to insects or trees, what US agencies have done so?

8. The FDA website page Scientific Evidence for Cell Phone Safety<https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety<https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety>> has a section entitled “No New implications for 5G”. Does the FDA believe that 5g is safe or that 5G has the same health issues as 3 and 4G ? What is the FDA opinion on the safety of wireless?

9. What is the FDA opinion on FCC limits in terms of long term health effects. Does the FDA believe the current limits protect the public, children, pregnant women and medically vulnerable from health effects after long term exposure.

10. The FDA is aware that cell phone can violate FCC SAR limits at body contact on high power. The FDA has written that because there is a safety factor. What is the safety factor for the SAR the FDA relies on. At what SAR level above FCC limits will the FDA intervene?

11. What actions specifically is the FDA doing now in regards to 5G and cell phone radiation in terms of research review? How often will the FDA be releasing reports?

12. Will the FDA be evaluating the safety of 5G cell antennas? If so how? If not, what health agency is ensuring that 5G cell antennas are safe for people, wildlife and trees.

13. Cell phones and wireless devices emit several types of non ionizing radiation in addition to radiofrequency radiation. For example the devices emit magnetic fields and when a pregnant woman holds a laptop on her lap the measured fields can be high even into the baby. What agency ensures safety related to extremely low frequency (ELF-EMF) electromagnetic fields- also non ionizing? Currently we have no federal limit, no federal guidelines and confirmed associations with cancer and many other health effects. Kaiser Permanente researchers have published several studies linking pregnant women's exposure to magnetic field electromagnetic fields to not only increased miscarriage<https://www.nature.com/articles/s41598-017-16623-8<https://www.nature.com/articles/s41598-017-16623-8>> and but also increased ADHD<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2763232<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2763232>>, obesity<https://www.nature.com/articles/srep00540<https://www.nature.com/articles/srep00540>> and asthma<https://jamanetwork.com/journals/jamapediatrics/fullarticle/1107612<https://jamanetwork.com/journals/jamapediatrics/fullarticle/1107612>> in the woman's prenatally exposed children. A recent large scale study <https://www.sciencedirect.com/science/article/pii/S0013935120303662?fbclid=IwAR11X_74FIT7y_RpO9WvbkE8AmAlBHAVU67yjKW8A6ZWPnPsLRioLxGsy1o#<https://www.sciencedirect.com/science/article/pii/S0013935120303662?fbclid=IwAR11X_74FIT7y_RpO9WvbkE8AmAlBHAVU67yjKW8A6ZWPnPsLRioLxGsy1o#>> again found associations with cancer. Please clarify which US agency has jurisdiction over ELF-EMF exposures?

14. Will the FDA be initiating any research studies on 5G and health effects?

We as a health study commission on 5G/ take these duties very seriously. We are unbiased and we are seeking all answers and facts. We are requiring your answers to the above questions.

Thank you,

Denise Ricciardi

Committee Member appointed by Governor Sununu.